Stop patents on our food plants!

Research on patent applications from 2020 shows how industry escapes prohibitions in patent law

Authors Ruth Tippe, Anne-Charlotte Moy, Johanna Eckhardt & Christoph Then

Published by *"No Patents on Seeds!"*(www.no-patents-on-seeds.org)

LOGOS and names of the organisations added as being on our website

We would like to thank the Salvia Foundation for funding our research on patents.



Photo: Falk Heller, Argum

Table of Contents

Summary....3
Free the seeds! Safe the future of our food!....4
The controversy about patents on plants....6
The general problem....7
A global perspective....8
Success for *No Patents on Seeds!*....10
New legal loopholes....10
Differences between GE and Non-GE....11
Research on patent application filed on conventional breeding and published in 2020....12
Case study: How companies try to exploit the legal loopholes....14
The case of WO2020239495 from BASF/ Nunhems: Exploring the patent strategy....14
The legal situation....18
Time to act now!....21
Annex:....23
Tabled overview on 50 most relevant patent applications....23
Lack of democratic and legal oversight....27
New problems arising from the EU Unitary Patent....27
Glossary....28

Summary

Patents create monopolies: conventionally bred plants and animals claimed in patents can not be used by other breeders, gardeners or farmers for further breeding without the permission of the patent holder. In many cases, the patents also cover the use of the harvested plants for food production.

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. The development will also have consequences for the Global South. In this light, patents on seeds must be considered as one of the biggest risks to global food security and regional food sovereignty.

In June 2017, the Administrative Council of the EPO decided that patents on conventionally bred plants and animals should no longer be granted: A new Rule 28(2) was introduced into the Implementing Regulations of the European Patent Convention. The decision was a huge victory for the interests of the wider public, as well as the numerous organisations represented in the international coalition of *No Patents on Seeds!*. The decision was confirmed in 2020 by a decision of the Enlarged Board of Appeal, the highest legal body of the EPO (G3/19).

However, the decision did not go far enough. Specific reason for concern: The Administrative Council based its decision on a document prepared by the previous President of the EPO (CA/56/17) that still allows for patents on random genetic mutations. By the wording of this document no difference is made between spontaneous occurring gene variants and random mutations on the one hand and, on the other hand, technical interventions by means of genetic engineering (including genome editing). Therefore, as the current practice at the EPO stands, randomly mutated plants are considered as patentable inventions. There is already proof that the legal loopholes introduced by the Administrative Council allowed the EPO to grant patents such as on beer and barley, melons and lettuce derived from random methods of conventional breeding.

On the other hand, previous decisions of the Enlarged Board of Appeal (G2/07 & G1/08) make clear that only "*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.*" However, a purposeful insertion or modification of a gene is not possible with randomly mutated plants or other plants derived from conventional breeding which typically have to undergo further crossing and selection before the trait as desired is achieved.

As shown in the overview of patent applications provided in this report, there is no doubt that companies like BASF, Bayer-Monsanto, DowDupont (Corteva) or also KWS actively try its utmost to exploit these legal loopholes. As our research shows, companies now use specific wording in their patent applications to mix technical elements (such as usages of CRISPR/ Cas) with standard methods of conventional breeding to give the impression of a technical invention. Companies thereby systematically try to obscure the distinction between conventional breeding and genetic engineering. In these cases, all plants (or animals) with the characteristics as described in the patent, are claimed as an invention. In most cases, additional elements are introduced as 'technical toppings' to simulate real inventions.

The strategy of industry also causes major problems in regard to the scope of patents: Patents granted on plants (or animals) derived from technical processes may encompass plants (or animals)

sharing the same characteristics obtained by conventional breeding. Even though these are not deemed patentable, they still may fall under the scope of a patent.

The report gives an overview on patent applications filed on conventional breeding of plants and animals which were published in the year 2020 and may be granted by the European Patent Office within the next years.

Further, it is shown that within the last ten years, around 100 patent applications concerning conventional plant breeding where filed each year. It can be expected that around 30 to 50 percent of these patents may be granted. As research in data bases shows, some of these patents may concern several dozen of even more than hundred varieties.

Since the new Rule 28(2) will only be applied on patent filed after July 2017, it might take the EPO more than ten years to sort out the legal loopholes by further decision making. So far, there are no decisions yet on any patents filed since that, not a single relevant patent application has been granted or rejected until the end of 2020. Therefore, it has to be expected that waiting for a final decision on relevant cases might prolong legal uncertainty for another ten years.

This means that hundreds of further patent applications will be filed and many patents may be granted before legal clarity can be achieved. This would be unacceptable for traditional breeders, farmers, patent applicants as well as for *No Patents on Seeds!*.

If these patents are not stopped by now, there will be huge implications for breeders, farmers and consumers which all get more and more dependent on the big companies which can control access to the biological resources needed for further breeding. Therefore, political decisions have to be taken as soon as possible, not waiting for the EPO to close the legal loopholes just case by case.

Otherwise, due to continued legal uncertainties, political controversies or ongoing legal challenges, plant breeding might be hampered or even disabled, smaller breeders might loose their profitability. The future of food and agriculture, the livelihood of our society might become impacted, a risk being being fostered by ongoing climate change.

In its campaign, No Patents on Seeds! wants to continue to safeguard ‘freedom to operate’ for all European breeders, gardeners and farmers involved in conventional breeding, growing and conservation of food plants and farm animals. Access to biological diversity needed for further breeding must not be controlled, hampered or blocked by any patents.

The ‘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.

Free the seeds! Safe the future of our food!

No Patents on Seeds! wants to continue to safeguard ‘freedom to operate’ for all European breeders, gardeners and farmers involved in conventional breeding, growing and conservation of food plants and farm animals. Access to biological diversity needed for further breeding must not be controlled, hampered or blocked by any patents.

According to our analysis, there are three crucial areas that need to be changed to make current prohibitions of patents on conventional breeding of 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.

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/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 "absolute product protection" which 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.

The controversy about patents on plants

‘Patents on life’ claiming 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.[1] Nevertheless, the biotech industry, supported by patent attorneys and the European Patent Office (EPO), has succeeded in making patents on seeds a reality. These developments have been driven by vested interests: agrochemical companies, patent attorneys and the EPO all profit from the patent business. Meanwhile, according to official statistics, around 3900 patents on plants and 2000 patents on animals have been granted in Europe, most of them being genetically engineered.

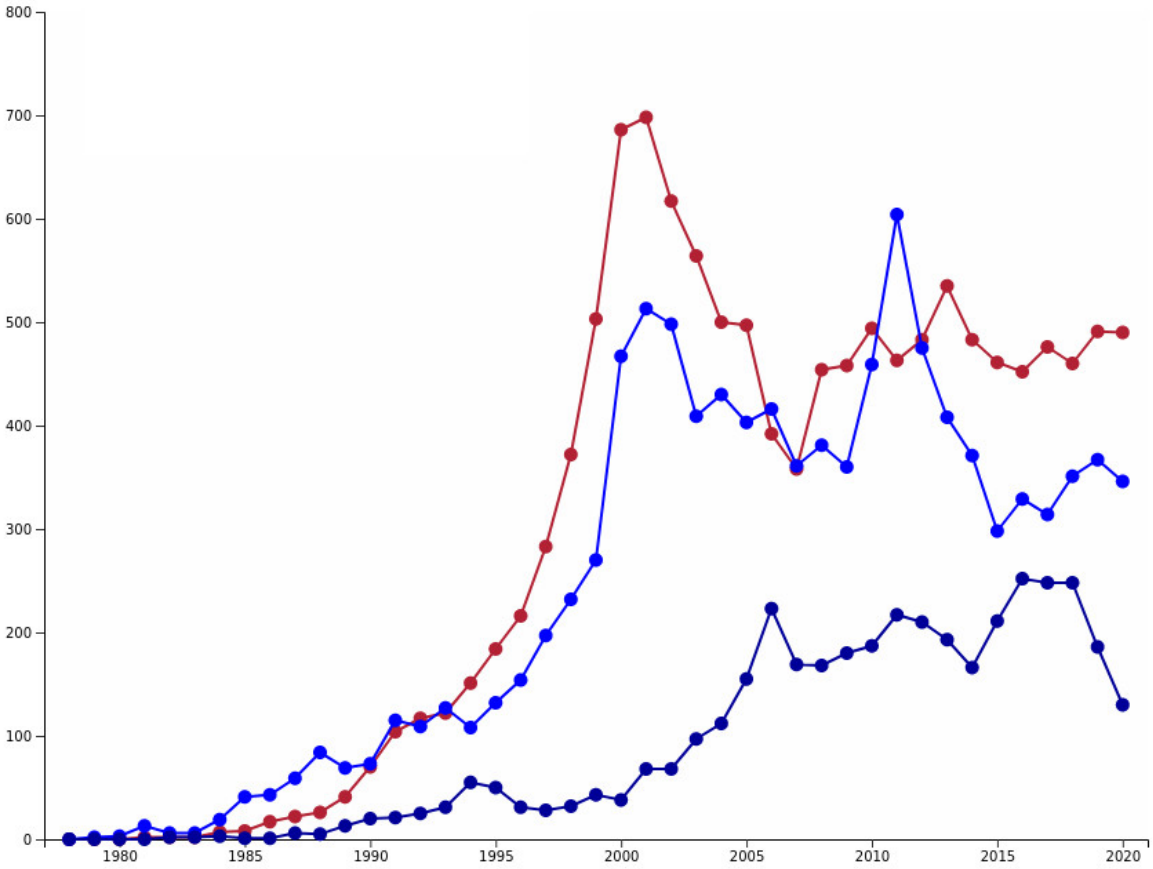


Figure 1: Patents on plants - number of patent applications for all plants under PCT/WIPO and at the EPO as well as of patents on plants granted by the EPO per year. Research according to official classifications (IPC A01H or C12N001582). Source: www.kein-patent-auf-leben.de/patentdatenbank/

There is an alarming trend that patents are extended to the area of conventional breeding: Within the last ten years, each year, around 100 new patent applications were filed which concern conventional plant breeding. Out of these more than 1000 patent applications, around 200 patents were granted already, although patents on ‘essentially biological’ (non-technical) plant and animal breeding are prohibited by European patent law (Article 53(b), EPC). Based largely on trivial technical features, such patents are frequently an abuse of patent law, i.e. they use patent law as a tool to

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

misappropriate biological resources needed for our daily food production. *No Patents on Seeds!* specifically aims to stop these patents.

Every patent on conventionally derived traits can simultaneously impact the breeding of dozens or even more than hundred of plant varieties.[2] Depending on the business strategy of the patent holder, licenses may be needed or access to biological resources blocked.

It should be noted that these patents are not just limited to plants and seeds, they also cover the harvest, and, therefore, the food (grain, fruits, drinks, vegetables and meat) that is produced. For example, in 2016, patents covering conventionally bred barley and the beer produced thereof were granted to the international companies Carlsberg and Heineken.

The general problem

Patents create monopolies: plants and animals claimed in patents can not be used by other breeders, gardeners or farmers for further breeding without the permission of the patent holder. Patents also create uncertainties: Pending patent applications and ongoing legal challenges can hamper plant breeders in their freedom to operate and prevent the generation of new varieties. In many cases, the patents also concern the use of the harvested plants for food production. This is entirely contrary to the current plant variety protection system (PVP), which in principle allows breeders to use the existing varieties needed for further breeding. Moreover, in regard to animal breeding, there are currently no restrictions on farmers using their livestock for further breeding or selling offspring to other breeders in Europe.

Despite patents on plant varieties are prohibited in Europe, the European patents granted on conventionally bred plants already concern several hundred varieties: As the PINTO database[3], established by European Seed Association (ESA) shows, at the end of 2020, there were 103 granted European patents listed in the database, but the number of varieties affected by these patents was more than 850 (see also table 1).

2 www.euroseeds.eu/pinto-patent-information-and-transparency-on-line/
3 www.euroseeds.eu/pinto-patent-information-and-transparency-on-line/

Table 1: Overview on 10 examples of granted European patents, affecting by European varieties plant varieties derived from conventional breeding (Source: www.euroseeds.eu/pinto-patent-information-and-transparency-on-line/)

Patent	Content	Company	Number of varieties concerned
EP2961263	Lactuca sativa with resistance to downey mildew	Bejo Zaden	121
EP2515630	Genetic markers associated with drought tolerance in maize	Syngenta	93
EP2451269	Plant resistant to a pathogen	Syngenta	56
EP1804571	Resistance to virus in Capsicum plants	Monsanto	55
EP2242850	Maize plants characterized by quantitative trait loci (QTL)	Syngenta	39
EP0921720	Aphid resistance in composites	Rijk Zwaan	38
EP1525317	Clubroot Resistant Brassica Oleracea Plants	Syngenta	37
EP2586294	Peronospora resistance in Spinacia	Rijk Zwaan	27
EP2164970	F. Oxysporum resistant Melons	Syngenta	23
EP1973397	Novel cucurbita plants	Syngenta	21

A global perspective

Corporations such as Bayer (Monsanto), Corteva (DowDupont), BASF and Chemchina (Syngenta) will prevail 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 from all over the world.[4] Moreover, they could shut down free access to biological diversity needed by other breeders if they also own patents on seeds. A similar process is happening in livestock breeding where companies, such as Genus and Hendrix Genetics, have increasing influence on the international market for breeding pigs, poultry and cattle.

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.

The numbers of all plant patent applications on plants per year is much higher for the agrochemical companies (such as Bayer) compared to traditional breeders. As experience shows, the dynamics within the patent regimes are mostly in favour of the larger companies (see figures 2 and 3).

4 See also: https://etcgroup.org/sites/www.etcgroup.org/files/files/etc_platetechtonics_a4_nov2019_web.pdf

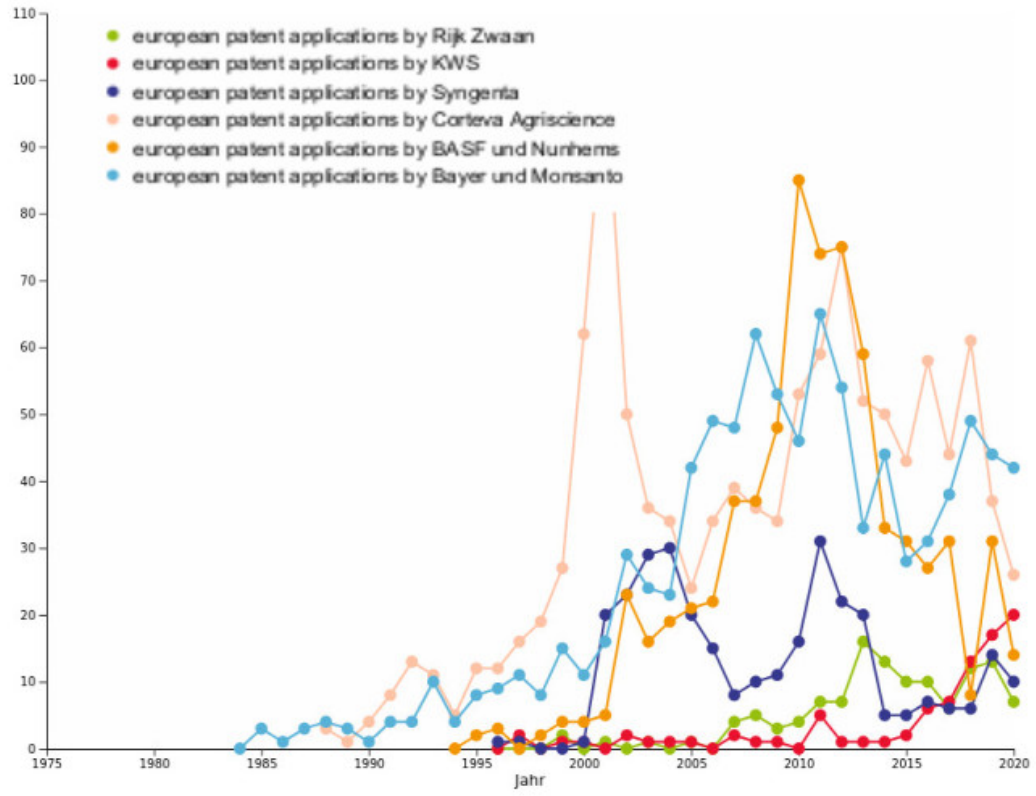


Figure 2: Patents on plants - number of patent applications for all plants under PCT/WIPO categorised by companies per year. Research according to official classifications (IPC A01H or C12N001582). Source: www.kein-patent-auf-leben.de/patentdatenbank/

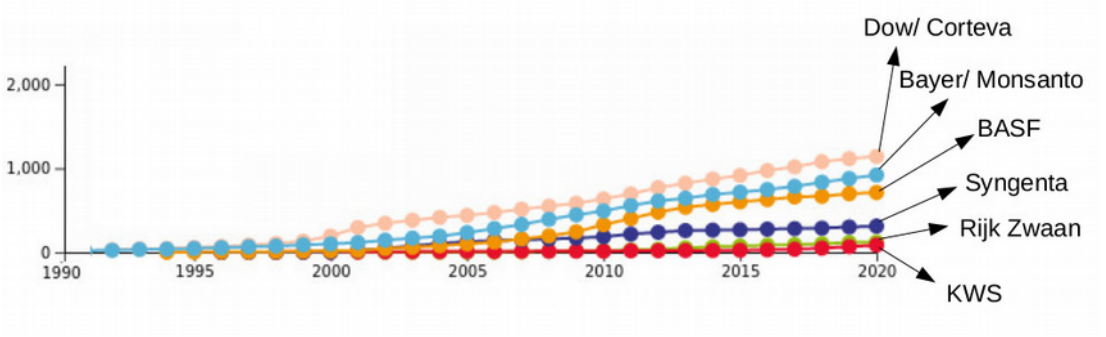


Figure 3: Patents on plants - number of patent applications for all plants under PCT/WIPO categorised by companies, per year, accumulated since 1990. Research according to official classifications (IPC A01H or C12N001582). Source: www.kein-patent-auf-leben.de/patentdatenbank/

The development will also have consequences for the Global South, where many countries have adopted legislation to allow patents on seeds. Recent findings[5] indicate that 60% of the 126 countries in the Global South for which data were available, are ready to allow the patenting of

5 https://onlinelibrary.wiley.com/doi/full/10.1111/jwip.12143

plants, or parts thereof, and many such patents have been identified. This could threaten food sovereignty in these countries as well as the regional traditions of 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 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.

Success for *No Patents on Seeds!*

No Patents on Seeds! was initiated as a European coalition in 2007, with the aim of stopping patents from being granted on the conventional breeding of plants and animals. As the number of filed patent applications and patents granted on plants and animals derived from 'non-technical' but 'conventional' breeding grew, so did the objections. It became obvious that these patents were not based on real 'inventions', but rather represented an abuse of patent law for the misappropriation of basic resources and common goods needed for daily life. Criticism of the practice started to become more and more vocal, with support coming from civil society, farmers, breeders as well as EU institutions and national governments.

In June 2017, the Administrative Council of the EPO decided that patents on conventionally bred plants and animals should no longer be granted. This decision was based on the wording of the European Patent Convention (EPC), which prohibits patents on 'essentially biological' breeding (Art 53 b). The decision of the Administrative Council to change the Implementing Regulations of the EPC by adding a new Rule 28(2) was a huge victory for the interests of the wider public, as well as the numerous organisations represented in the international coalition of *No Patents on Seeds!*. It also reflected the demands of the EU, as set out by the EU Commission[6], the EU Parliament[7] and the Council of the EU Member States[8]. In 2020, the decision of the Administrative Council was also confirmed by the Enlarged Board of Appeal (G3/19) which is the highest legal body of the EPO.

New legal loopholes

However, the decision did not go far enough. Specific reason for concern: The Administrative Council based its decision on a proposal made by the previous President of the EPO that still allows for patents on genetic variations ('mutations').[9] No difference is made between naturally occurring gene variants and random mutations on the one hand and, on the other hand, technical interventions by means of genetic engineering, including the new methods such as genome editing (e.g. CRISPR/ Cas gene scissor applications).

This legal loophole has far reaching consequences. Within their patents, companies now use specific wordings to mix technical elements (such as usages of CRISPR/ Cas) with standard methods of conventional breeding: (1) Seeds, plants and harvested food derived from random processes, are claimed as 'inventions'. (2) Even if only crossing and selection (of the phenotype and/or the genotype) or random mutations were needed to achieve the desired traits, in many cases,

6 http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52016XC1108(01)
7 www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P7-TA-2012-0202+0+DOC+XML+V0//EN and www.europarl.europa.eu/sides/getDoc.do?type=TA&reference=P8-TA-2015-0473&language=EN&ring=P8-RC-2015-1394
8 www.epo.org/news-issues/news/2017/20170629.html
9 https://www.epo.org/modules/epoweb/acdocument/epoweb2/256/en/CA-56-17_en.pdf

additional ‘technical toppings’ such as genome editing or methods of transgenesis are introduced. Thereby, companies systematically try to diffuse the distinction between conventional breeding and genetic engineering and try to exploit the legal loopholes as created by the Administrative Council.

Differences between GE and Non-GE

In practice, a clear distinction between the profoundly different areas of ‘biological’ processes (conventional breeding) and technical interventions (old and new methods of genetic engineering) can be easily made: conventional breeding starts from a broad range of genetic diversity, which is needed to perform further crossing and selection to derive to a desired trait (breeding characteristics). Whereas technical methods of genetic engineering, involve creating plants or animals by inserting additional DNA sequences or the direct and targeted change of specific genes in the genome may directly generate a new trait in a given plant or animal. The profound differences between conventional breeding and the technical methods of GE (in this case genome editing) is also underlined by the noble price as granted in 2020 to two of the inventors of CRISPR/ Cas.

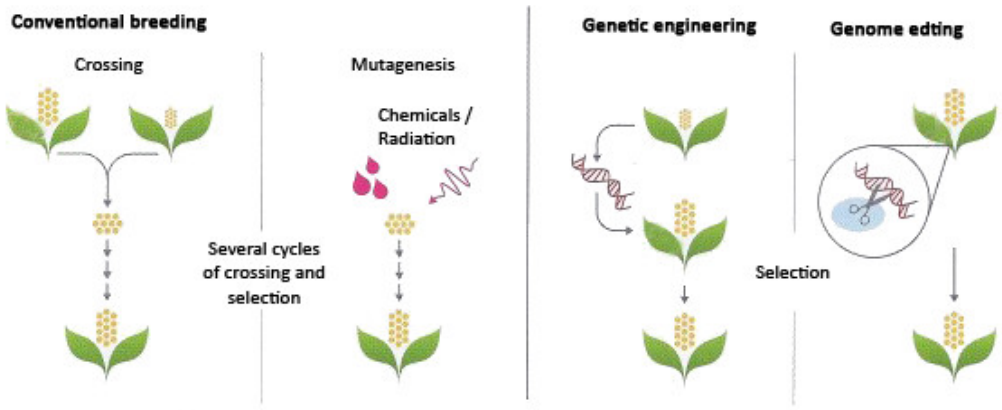


Figure 4: Differences between conventional breeding (including random mutagenesis) versus genetic engineering (including genome editing): conventional breeding always needs several cycles of crossing and selection to derived to a desired trait, while GE may directly insert new characteristics into a plant.[10]

If this distinction is not established in patent law, breeders, gardeners and farmers will still be trapped by patents even if they avoid genetic engineering methods, e.g. transgenesis or genome editing. Under these conditions, even seeds derived from conventional breeding can no longer be accessed under the conditions of PVP regime, their use will be dependent on contracts with the owner of the patents. The patent holders can hamper, restrict or block access in accordance with their own financial interests. The same problem will occur with livestock if used for breeding. Crucially, there might even be an accumulation of several patents for plants or animals after further crossing.

10 adopted from Genomxpress Scholae Nr 5, funded by the German Ministry for Education and Research (BMBF)

Research on patent application filed on conventional breeding and published in 2020

No Patents on Seeds! carried out in-depth research on international patent applications 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 can cover up to 100 countries where the patent protection could become valid. The WIPO itself does not grant any patents, but for many companies it is a first step for filing patent applications in multiple countries around the world. Looking at recent figures, it can be estimated that two thirds of patents filed for plants at the WIPO will also become European Patent applications. On average, around one third of the European patent applications in this field will be granted (for comparison see figure 1). Whilst our research can be seen as representative for recent international patent applications in this field, it is nevertheless hard to predict which of these applications will ultimately be granted by the EPO.

The research is based on searches of the relevant databases with specific International Classifications (IPC = A01H or C12N15/82), names of relevant companies as well as on the analysis of the content of several hundred patent applications. From the beginning of 2020 until beginning 2021, around 300 patent applications were published for plants and plant breeding, with around 80 applications covering conventional breeding. Our research found that around 50 patents on plants and plant breeding were the most relevant for this report. As not so relevant patent applications were considered targeting non-food plants (such as ornamental plants, tabacco, hemp) or applications which were not clearly defined in their technical approach.

The selected 50 patent applications concern fruits such as melons or grape vines, vegetables such as spinach, broccoli, lettuce, pepper and tomatoes and also cereals such as wheat, rice, maize maize or soybean and oilseed rape.

The patent were filed by huge corporations such as Bayer (Monsanto), BASF, DowDupont, Syngenta, by breeding companies such as KWS or Rijk Zwaan and others. Figure 5 lists the companies with more than one relevant patent application in 2020.

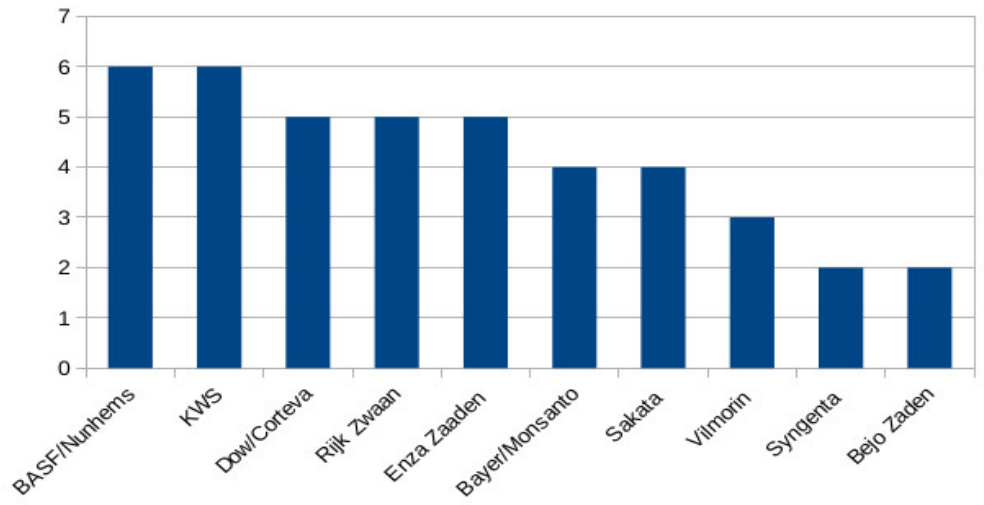


Figure 5: Companies with more than one patent application on conventional breeding of plants, published in 2020.

To categorize the patent applications five criteria were applied:

- The examples from the patent description were used to decide whether the patent is based on conventional breeding (crossing and selecting, also including random mutations) or on genetic engineering (including genome editing).
- The examples from the patent description were also analysed in regard to specific applications of random mutagenesis, since this method is a crucial loophole to escape current prohibition under Article 53(b) and Rule 28 (2).
- The claims were analysed to find out whether, in line with the examples, a distinction is made between conventional breeding and genetic engineering. If no such distinction is made, it is assumed that these differences are intentionally blurred to claim all plants with specific traits (breeding characteristics).
- The claims were also analysed to assess if patents explicitly claim viable cells which can be used to regenerate whole plants.
- Finally, also the number of cases in which food is explicitly claimed, was used as criterion.

It is evidenced that in more than 90 percent, the claims are blurring the distinction between conventional breeding and GE, while only in around 10 percent GE also was used additionally, to establish the desired trait. In more than 30 percent random mutagenesis was used together with crossing and selection. Explicit claims on cells were filed in more than 50 percent. In around 60 percent, the patents explicitly extend to harvest and food derived from the plants. The result is displayed in figure 6.

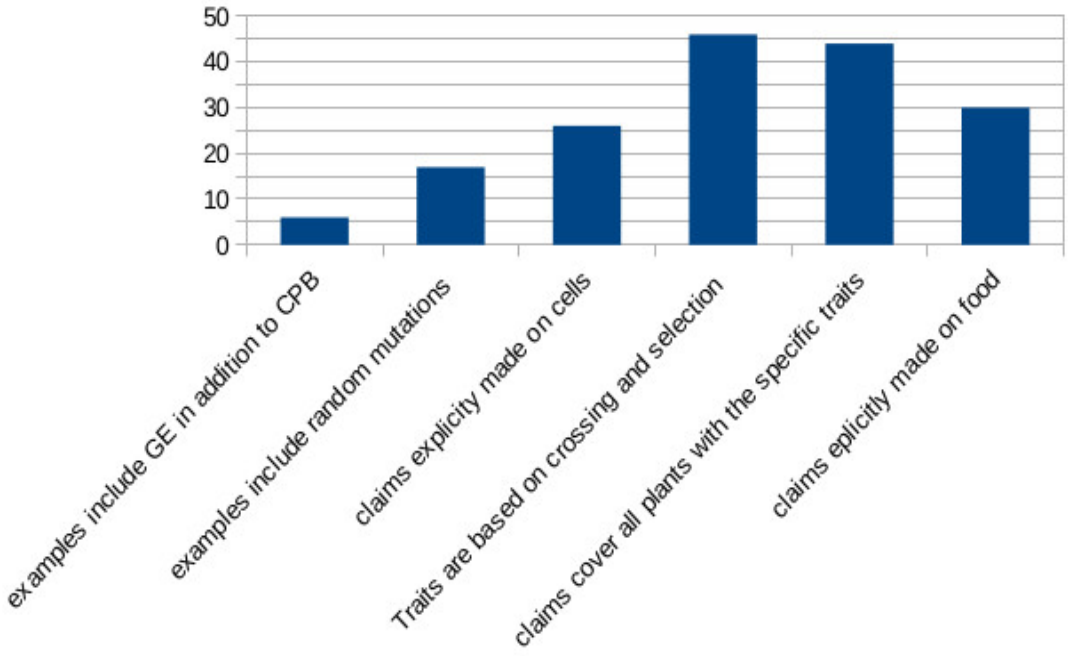


Figure 6: Analysis of 50 international patent applications concerning food plants, published in 2020, designated to become European patents. It is evidenced that in most cases, the claims are directed to all plants inheriting specific traits (breeding characteristics), no matter how they were achieved. The strategy behind these patents is to systematically blur the fundamental differences between CPB and GE, to escape the prohibitions in European patent law in regard to conventional breeding.

The analysis shows to which extent the companies try to exploit the loopholes in current prohibitions which were introduced by documents adopted by the Administrative Council. It is evidenced that the limitation of the scope of patents, the definition of essentially biological methods and the exclusion of viable cells from patentability are crucial to achieve legal clarity and certainty in regard to the prohibitions of Article 53(b) and Rule 28(2). If these problems are not solved, not only hundreds of conventionally bred varieties will be affected by European patents, but, in many cases, also the food derived thereof.

Case study: How companies try to exploit the legal loopholes

As shown above, in the overview of patents applications provided in this report (see also tabled overview in the Annex), there is no doubt that industry actively tries its utmost to exploit these legal loopholes. In most cases, additional elements are introduced as 'technical toppings'.

This can be evidenced by comparing the description of the patent applications ("examples") with the wording of the claims: Within 50 relevant patent applications on conventional plant breeding (CPB) in 2020, 48 patents are based on crossing and selection. In 17 cases random mutagenesis was applied in combination with crossing and selection (see Figure 6). Only in 6 cases it was shown in addition, that the desired traits could also be achieved by direct insertion using GE.

However in 46 out of 50 patent applications, the claims are covering both, GE and CPB (see figure 6). Thus the claims, in most cases, are directed to all plants inheriting specific traits (breeding characteristics), no matter how they were achieved.

The strategy behind the wording of these patents is to systematically blur the fundamental differences between CPB and GE. Thereby, these patent application aim to escape the prohibitions in patent law in regard to conventional breeding, by using the loopholes as established by the decision making of the Administrative Council of the EPO such as random mutagenesis. In result, the patent can be granted even if the plants are derived from random processes, based on several cycles of crossing and selection to achieve the desired traits. This problem is exemplified by a case study on Patent application WO2020239495 from BASF/ Nunhems below.

The case of WO2020239495 from BASF/ Nunhems: Exploring the patent strategy

An typical example for relevant patent applications is WO2020239495 from BASF/ Nunhems on 'oomycete resistance in tomato and cucumber'. Oomycetes are known to cause plant diseases such as downy mildew and late blight.

In short:

- The examples as provided in the patent start from seeds and plants with known resistance to oomyctes, originally collected in India, derived from an US gene bank. These plants were then used for further crossing and selecting. Additional gene analysis (genotyping) was performed and pest infestation was tested (phenotyping) by exposing the plants to oomyctes. After that, random mutation was performed, to achieve further relevant gene variants, followed by further crossing and selection to establish the intended trait. In result, the trait as described is based on crossing and selection, with and without random mutagenesis. No

targeted method to directly introduce a trait by genetic engineering (including genome editing) was used.

- The claims are not restricted to any method, but all plants are claimed which inherite the traits and characteristics as described. Within the claims, crossing and selection is not mentioned. Instead, the methods which are explicitly mentioned are referring to the legal loopholes as created by the document as published by the Administrative Council (CA/56/17): Claims 7 and 17 are directed to plants derived from random mutagenesis, genome editing or being generated from cell cultures.

If the patent is granted, it would cover all plants, seeds and fruits, with the traits as described, also those derived from random processes.

According to the examples the following steps for breeding were performed:

1. Breeding of cucumber with increased resistance to downy mildew (DM):
1.1. Seeds for cucumber being resistant to DM originating from Assam, India (PI 197088) were crossed with a line of cucumber which is susceptible to DM.
1.2. Repeated crossing and selection was performed to develop homogeneous lines for further breeding.
1.3. A quantitative trait was identified being responsible for resistance to downy mildew. It is sited on one chromosome with three genes being involved.
1.4. The plants were exposed to *Pseudoperonospora cubensis* which are known to cause DM.
1.5. Plants with resistance were identified (phenotype) and used for further analysis of the genotype, followed be further phenotyping, assisted by biochemical analysis.
1.6. Expression of the genes involved was measured and correlated to the phenotype.

2. Breeding of tomatoes with increased resistance to late blight (LB):
2.1. Similar genes as detected in the cucumber were screened in tomatoes and identified.
2.2. To confirm the function of the relevant genes in tomatoes, crossing and selection was performed to derive to homozygous lines with mutant variants of the genes. It is not described if these mutations are derived from spontaneous mutation, from random mutagenesis or from targeted intervention by methods of genetic engineering (including genome editing).
2.3. The resulting plants were exposed to *Phytophthora infestans* which is known to cause LB. Plants with reduced lesions were identified (phenotyping).
2.4. Genotyping showed some resistance to LB to correlate with the mutations.

3. Further breeding with cucumber
3.1. Plant material from cucumber plants was exposed to chemical mutagenes, followed by further selection (tilling) to identify further mutations in the relevant genes.
3.2. Further crossing and selection was performed to derive to the desired trait. It was shown that the trait is not only influenced by the mutations but also by its genetic background.

Summary:
Several genes and gene variations (mutations) were identified in cucumber and tomato to play a role in DM and LB. In this case, the starting point was a native trait from Indian accessions. To derive to plants with desired traits (resistance to DM and LB) intensive crossing and selection was performed, in combination with phenotyping and genotyping. Thereby, homozygous alleles and

breeding lines with suitable genetic backgrounds could be achieved. No targeted methods of genetic engineering (including genome editing) were applied.

The wording of the claims

The claims are not restricted to any method.

Claims 1-14 are directed to tomatoes:

- Claim 1 and claim 2 are directed to all tomato plants with the identified gene variants, no matter how they are derived from.
- Claim 3 are directed to tomato plants with reduced susceptibility to phytophthora infestans and homozygous alleles as decribed.
- Claim 7 is directed to plants with the gene variants as described derived from "*chemical mutagenesis, radiation mutagenesis, tissue culture or targeted genome editing techniques such as Crispr based techniques*". Apparently this wording closely follows the logic of the legal loopholes as created by the documents as published by the Administrative Council.
- Claim 8 is directed to all seeds or plants derived from any method as described. If this claim is granted, all plants with the traits and characteristics as described are within the scope of the patent.
- Claim 9 and 10 are directed to all parts and including the fruits.
- Claim 11 is directed to vegetatively propagated plants with the traits and characteristics as described.
- Claim 12 and 13 are directed to any method to produce tomato plants or tomato fruits by using plants with the described gene variants. However, crossing and selection as performed in the examples, are not mentioned
- Claim 14 claims methods for selecting plants with the desired traits.

Claim 15 to 17 are directed to cucumber plants, using similar wordings as the claims above. Claims 17 again lists "*chemical mutagenesis, radiation mutagenesis, tissue culture or targeted genome editing techniques such as Crispr based techniques"*.

Summary:

The claims avoid any mentioning of crossing and selection. Instead all plants with the traits and characteristics as described are claimed. The only methods which are explicitly mentioned in the claims ("*chemical mutagenesis, radiation mutagenesis, tissue culture or targeted genome editing techniques such as Crispr based techniques"*) are referring to the loopholes as created by the documents as published by the Administrative Council (CA/56/17). If the patent is granted as applied, it will cover all plants, seeds and fruits, also those derived from random processes.

Before the patent is granted, it is likely that a disclaimer might be inserted as described in the current Guidelines for Examination of the EPO, to exclude plants derived from methods of 'essentially biological processes' or which were originally found in the gene bank. However, this would not alter the scope of the patent substantially, as long as plants derived from random mutagenesis are be regarded as technical (patentable) inventions. Under these circumstances, the BASF still could enjoy full patent protection.

There is already proof that the legal loopholes introduced by the Administrative Council still allowed the EPO to grant patents or reject oppositions after June 2017, e.g. on beer and barley[11], melons[12] and lettuce[13] derived from methods of conventional breeding.

Table 2: Examples of patents granted on plants derived from conventional breeding using random mutagenesis after Rule 28(2) was adopted by the Administrative Council in June 2017, including cases in which opposition was rejected

Patent number and Company *	Content	Date: grant intended announced	Date: grant of patent published
EP 2373154, Carlsberg/Heineken	Barley & Beer	Rejection of the opposition: 2.10.2018	20.4. 2016
EP 2384110, Carlsberg/Heineken	Barley & Beer	Rejection of the opposition 2.10.2018	20.4. 2016
EP2547766, BASF	Herbicide resistance in Brassica	27.07.2017	27.12.2017
EP 2455475, Enza Zaden	Melon plants with disease resistance	23.10.2017	03.01.2018
EP 2966992, Rijk Zwaan (opposed by NPoS)	Lettuce with germination at higher temperature	22.12.2017	06.06.2018
EP 2882280 Green4health B.V.	Ripening-impaired mutant tomato	29.01.2018	18.07.2018
EP 2931902 SESVanderHave N.V.	Herbicide resistant sugar beets	23.03.2018	01.08.2018
EP 3016506, INRA	Mutation in the FIDG gene	16.04.2018	12.09.2018
EP 2992756 House Foods Group	Onion with reduced pungency	19.04.2018	26.09.2018
EP 2681234 Enza Zaden, Keygene	Powdery mildew resistance melon	25.04.2018	03.10.2018
EP 2681233 Enza Zaden, Keygene	Powdery mildew resistance cucumis	15.05.2018	24.10.2018
EP 2475243, Rijk Zwaan	Tomato with long shelf life	30.05.2018	07.11.2018
EP 2700721, Cibus	Herbicide resistant plants	26.07.2018	02.01.2019
EP 2484200, Rijk Zwaan	Lettuce with tolerance to disorders	21.09.2018	13.03.2019

*** It appears that the EPO followed a policy of prioritsing the granting of patents to Dutch companies in this period of time. Possibly, the EPO adopted this policy to raise awareness that not only big international companies are interested in being granted of such patents. However, in same period of time, most patent applications in conventional plant breeding were filed by BAYER (Monsanto/ Seminis) see: www.no-patents-on-seeds.org/en/node/628.**

Due to open legal questions around the decision G3/19, in the second half of 2019 and in 2020, hardly any further patents were granted on conventionally bred plants. However, this moratorium was ended in June 2020 and, in 2021, already further patents on plants with traits derived from non-technical processes were announced to be ready for granting by the EPO.

11 https://www.no-patents-on-seeds.org/en/patent-cases/beer
12 https://www.no-patents-on-seeds.org/en/patent-cases/melon
13 https://www.no-patents-on-seeds.org/en/patent-cases/salad-hot-climate

The legal situation

According to our analysis, there are three crucial areas that need to be changed to make current prohibitions of patents on plant and animal varieties and essentially biological methods for breeding effective:

- Definition of "essentially biological processes"
- Definition of 'products' used or derived from breeding
- Limiting the scope of protection

1. Definition of "essentially biological processes"

In 2010, the Enlarged Board of Appeal issued its decisions G2/07 and G1/08 which provided a definition of 'essentially biological processes' for breeding plant and animals (non-patentable) to distinguish them from technical inventions (patentable). It came up with a pretty wording which explains that patentable inventions are, for example, " (…) *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."*

In the final statements of the decisions (headnote 3) it is stated that if there is a "*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."*

This ruling is still binding for the decision making of the EPO. Having in mind the different categories in breeding as explained above (Figure 4), there is no doubt that conventional breeding in all variants (crossing and selection with and without mutagenesis) is excluded from patentability under Article 53(b). The technical potential of GE to purposeful insert or modify one or more genes is used to define the legal exclusion of 'essentially biological processes'. This is also in line with the interpretation of the European Biotech Directive 98/44/EC presented by the European Commission (EC) in November 2016[14], which concludes that only methods of genetic engineering which directly intervene in the genome of plants and animals are regarded as patentable. The same perspective is taken by the EU Parliament[15] and the Council of the EU Member States[16].

However, in the preparation of the decision on Rule 28(2) in June 2017, the Administrative Council adopted a document (CA/56/17)[17] which is in contradiction with this definition. The most problematic passage reads: "*Mutagenesis as such is considered to be a technical process which results in a modification of the genome of the plant or animal. This applies to 'traditional' methods like irradiation or chemical mutagenesis, but even more so to molecular methods like Zinc Finger Nucleases, CRISPR, TALEN, ODM (oligonucleotide directed mutagenesis), etc. which require man-made molecules for targeted mutagenesis.*" There is no doubt that this document and two other

14 http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52016XC1108(01)

15 www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P7-TA-2012-0202+0+DOC+XML+V0//EN and www.europarl.europa.eu/sides/getDoc.do?type=TA&reference=P8-TA-2015-0473&language=EN&ring=P8-RC-2015-1394

16 www.epo.org/news-issues/news/2017/20170629.html

17 https://www.epo.org/about-us/governance/documentation/ac-documents.html

documents published by the Administrative Council (CA/PL 4/17 and CA/PL 4/20) are in conflict with the G2/07 and G1/08 decisions. As shown in Table 2, these document are driving current decision making at the EPO by opening up the loopholes which now get exploited by industry as shown in Figure 5.

From a purely legal perspective, the decision G2/07 and G1/08 are the final decisive documents which should overrule the documents as published by the Administrative Council (such as (CA/56/17). Therefore, the contradictions between the documents might become sorted out by further case law and patent oppositions. However, according to another decision of the Enlarged Board of Appeal (G3/19), Rule 28(2) only has to be applied on patents applied after July 2017.

So far, there are no decisions yet on any patents filed since that, not a single relevant patent application has been granted or rejected until the end of 2020. Therefore, it has to be expected that waiting for a final decision on relevant cases might prolong legal uncertainty for another ten years. This uncertainty is also underlined by the new Guidelines for Examination, which will enter into force on 1 March 2021. In its chapter G, these Guidelines seem to aim to find a compromise between the different documents. But the actual wording adds much moreto the confusion without bringing further clarification.[18]

This means that hundreds of further patent applications will be filed and many patents may be granted before legal clarity can be achieved. In the light of the legal analysis as provided and the history of the decision on Rule 28(2), this would be unacceptable for traditional breeders, farmers, patent applicants as well as for *No Patents on Seeds!*. Due to legal uncertainties, political controversies or ongoing legal cases, plant breeding might be hampered or even disabled, smaller breeders might lose their profitability. The future of food and agriculture, the livelihood of our society might become impacted, a risk being being fostered by ongoing climate change.

2. Definition of products used or derived from breeding

Further, in regard to Rule 28(2) and the document as adopted by the Administrative Council (CA/56/17), further clarification is also needed for paragraph 51 of the submission by the former President which reads: *“In vitro plant and animal cells are regarded as patentable microbiological inventions”*.

Consequently, plant and animal cells cultured in vitro, which are used in or emanating from ‘essentially biological processes’, would remain patentable. There is not any justification for introducing such a specific exemption, which may render the effects of Rule 28(2) ineffective in many cases.

This problem is acknowledged by the new Guidelines for Examination. In its chapter G, the Guidelines are stating that no patents on viable cells stemming from plants and animals derived from conventional breeding can be granted if these cells can be used to establish whole plants and animals.[19] However, the Guidelines might be changed from year to year. Therefore, further clarification will be needed by the Administrative Council that indeed all relevant breeding materials, including viable cells, are excluded under Article 53(b) and Rule 28(2).

18 https://www.epo.org/law-practice/legal-texts/guidelines/guidelines-preview.html
19 https://www.epo.org/law-practice/legal-texts/guidelines/guidelines-preview.html

3. Limiting the scope of protection

As evidenced by Figure 4, the current strategy of companies filing patents on conventional breeding, is based on blurring the differences between GE and CVP by adding technical toppings and claiming all plants with specific traits (breeding characteristics). There is further evidence from patent applications on genome editing, that this strategy is also followed in the opposite direction: In several cases, claims of patents filed on plants derived from GE techniques (involving for example CRISPR/Cas) are extended to plants or animals which may have same characteristics, but are derived from conventional breeding. Some examples are listed in Table 3.

Table 3: Examples of patent applications for genome editing also concerning conventional breeding

Patent number	Company	Content
WO 2014110552	Recombinetics	Hornless cattle for natural and synthetic genetic applications.
WO2017040695	Recombinetics	Genetic variants in cattle such as polled, climate adaption and fertility.
WO2017044744	Monsanto	Mildew resistance in maize
WO2017106731	Monsanto	Northern leaf blight resistance
WO2018031874	Monsanto	Resistance to 'late wilt' in maize
WO2014006159	Bayer	Changed oil composition in soybean
WO2015000914	Bayer	Changes in flowering times
WO2016176476	Bayer	Changed oil composition in oilseed rap

Therefore, the granting of European patents has to be restricted in a way that avoids any overlap between what can be patented and what is excluded from patentability under Article 53(b) and Rule 28(2). Otherwise, the scope of patents granted on plants (or animals) derived from technical processes may encompass plants (or animals) sharing the same characteristics obtained by "essentially biological processes". Even though these are not deemed patentable, they still may fall under the scope of a patent.

We are aware of the possibility of the introduction of a disclaimer into the patent claims which might help in some cases. However, doubts remain if this will be the best solution for all future cases. It would require to assess the need to introduce disclaimers in each and every patent in accordance with the Guidelines for Examination. It is likely that, over the time, legal uncertainty will be increased due to an increasing number of relevant applications.

Therefore, we request the Administrative Council to think about other solutions, considering the general difference between claims on the processes and claims on the products. In the context of Article 53(b) absolute product protection is highly problematic: If 'absolute product protection' is provided for plants and animals produced by methods of genetic engineering, then the scope of these patents can also cover plants and animals derived from "essentially biological processes" with the same or similar characteristics. Therefore, to make the exclusion in Article 53(b) effective, the scope of patents should be restricted to the technical process used to produce plants or animals. For further explanations see the report of *No Patents on Seeds!* (2018).[20]

20 www.no-patents-on-seeds.org/sites/default/files/2018-06/Report_No%20patents%20on%20broccoli,%20barley%20and%20beer_2018.pdf

Time to act now!

In the last ten years, around 100 patent applications on plants where identified each year which concern conventionally bred plants. It can be expected that around 30 to 50 percent of these patents will be granted. As research in data bases shows, some of these patents may concern several hundred varieties.

If these patents are not stopped, there will be huge implications for breeders, farmers and consumers which all get more and more dependent on the big companies which can control access to the biological resources needed for further breeding.

Due to legal uncertainties, political controversies or ongoing legal cases, plant breeding might be hampered or even disabled, smaller breeders might loose their profitability. The future of food and agriculture, the livelihood of our society might become impacted, a risk being being fostered by ongoing climate change.

In its campaign, No Patents on Seeds! wants to continue to safeguard ‘freedom to operate’ for all European breeders, gardeners and farmers involved in conventional breeding, growing and conservation of food plants and farm animals. Access to biological diversity needed for further breeding must not be controlled, hampered or blocked by any patents.

The ‘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 of patents on conventionally breeding of 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.

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/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 “absolute product protection” which 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.

To put an end to the uncertainty and the legal chaos surrounding EPO decision-making, the European governments have to clarify the rules for interpretation of the EPC via a new decision by the Administrative Council.

If this is not feasible, a change the EPC can be decided by a Conference of the Contracting States. This conference has the power to change the text of the EPC by a majority vote to introduce stronger wording for the exclusion of plants and animals from any patents.

Both ways might be successful in excluding plants and animals derived from conventional breeding from patentability. It does, however, mean that political decision-makers must act with meticulous care and decisiveness to overcome strong lobbying from the biotech industry and patent lobbyists to finally close all legal loop holes.

Annex:

Tabled overview on 50 most relevant patent applications

Table 6: overview on 50 most relevant patent applications claiming food plants derived from conventional breeding, published in 2020.

	Patent number Plant species Trait Specials	Company	Examples are based on crossing and selection	Examples combine random mutagenesis and crossing and selction	Examples additionally include genetic engineering e.g. gene insertion and genome editing	Claims cover both, GE and essentially biological processes	Claims explicitly cover viable cells	Claims explicitly cover food / harvest derived of (in addition to seeds)
1.	WO2020074237 Lettuce Downy mildew resistance	BASF/Nunhems	X	X		X		X
2.	WO2020120242 Pepper (Solanacea) seedless	BASF/Nunhems	X	X		X	X	X
3.	WO2020168166 clubroot resistant Brassica plants	BASF/Nunhems	X		(transgenic approach failed)	X		
4.	WO2020239496 Downy mildew resistance in Cucurbitaceae	BASF/Nunhems	X	X		X	X	X
5.	WO2020239495 oomycete resistance in tomato and cucumber	BASF/Nunhems	X	X		X	X	X
6.	WO2020249593 Tomato improved ripening	BASF/Nunhems	X	X		X		X
7.	WO2020006044 male sterilty system	Bayer	X			X	(X)	X
8.	WO2020006112 similar as above	Bayer	X			X	(X)	X
9.	WO2020132188 maize (sweet corn) with resistance to Northern leaf blight	Bayer/ Seminis	X			X	(X)	(X)
10.	EP3701791 pepper fruits comprising two different colors	Bayer/ Seminis	X					X
11.	WO2020036950 canola (oilseed rape) with blackleg resistance	Dow/ Corteva	X			X		
12.	WO2020036954 canola (oilseed rape) with blackleg resistance	Dow/ Corteva	X			X		
13.	WO2020056259 hybrid breeding in wheat and others	Dow/ Pioneer	X		X (CRISPR)	X	X	

	Patent number Plant species Trait Specials	Company	Examples are based on crossing and selection	Examples combine random mutagenesis and crossing and selction	Examples additionally include genetic engineering e.g. gene insertion and genome editing	Claims cover both, GE and essentially biological processes	Claims explicitly cover viable cells	Claims explicitly cover food / harvest derived of (in addition to seeds)
14.	WO2020139756 cotton resistant to Fusarium	Dow/Corteva	X			X		
15.	WO2020257273 pod shatter tolerant phenotype in Brassica	Dow/Pioneer	X					
16.	WO2020051166 traits of tolerance under water stressed conditions	Syngenta	X			X		
17.	WO2020078852 tomato with modified sugar content	Syngenta	X			(X)		X
18.	WO2020008078 modifying tuber shape of a potato	KWS	??		X	X		
19.	WO2020064687 glyphosate resistant beta vulgaris, sugar beet	KWS		X				
20.	WO2020157197 haploid inducer Brassica, Sorghum Helianthus	KWS	X	X		X		
21.	EP3718397 Wheat cytoplasmic male sterility restorer genes	KWS	X		X (but only to demonstrate gene function)	X	X	
22.	WO2020229533 Drought tolerance in maize	KWS	X	X	X	X only methods for producing		
23.	WO2020239680 haploid inducer maize, sorghum	KWS	X			X	X	
24.	WO2020025631 resistance to Cucurbit Yellow Stunting Disorder virus (CYSDV) in plants of the Cucurbitaceae	Rijk Zwaan	X		Only mentioned as possibility (also random mutagenesis)	X	X	X
25.	WO2020025632 Mutant allele leading to only male flowers in cucumber plant	Rijk Zwaan	X			X	X	
26.	EP3650463 Reversible genetic male sterility in Latuca, lettuce, endive, cichorium	Rijk Zwaan	X (also crossing via bumble bees)			X		
27.	WO2020128044	Rijk Zwaan	X			X	X	X

	Patent number Plant species Trait Specials	Company	Examples are based on crossing and selection	Examples combine random mutagenesis and crossing and selction	Examples additionally include genetic engineering e.g. gene insertion and genome editing	Claims cover both, GE and essentially biological processes	Claims explicitly cover viable cells	Claims explicitly cover food / harvest derived of (in addition to seeds)
	Spinach with resistance to Peronospora farinosa							
28.	WO2020193712 Brassica plants with resistance to downy mildew	Rijk Zwaan	X			X	X	X
29.	WO2020035145 lettuce with resistance to downy mildew	Enza Zaden	X		X (but only to demonstrate gene function)	X		X
30.	WO2020126500 lettuce with resistance to downy mildew	Enza Zaden	X		X (but only to demonstrate gene function)	X		X
31.	WO2020125925 iceberg lettuce easier to harvest	Enza Zaden	X				X	X
32.	WO2020148021 Tomato with resistance to Tobamo virus	Enza Zaden	X		X (but only to demonstrate gene function)	X	X	X
33.	WO2020239186 Melons with resistance to downy mildew	Enza Zaden	X	X		X	X	X
34.	WO2020099330 Potato with resistance to Phytophthora infestans	Bejo Zaden	X				Plants derived from vegetative propagation.	
35.	WO2020239215 spinach with resistance to downy mildew	Bejo Zaden	X			X	X	X
36.	WO2020077224 pepper plants with resistance against fusarium	Sakata	X			X	X	X
37.	EP3682732 downy mildew resistant cabbage	Sakata	X			X		X
38.	EP3721705 producing Lactuca plant seeds using megachile bees	Sakata	X (via pollination with bees, but only the process)					
39.	EP3756454 Hybrid production in broccoli	Sakata	X			X		X
40.	WO2020030804 Cauliflower resistance to Xanthomonas	Vilmorin	X	X		X	X	X

	Patent number Plant species Trait Specials	Company	Examples are based on crossing and selection	Examples combine random mutagenesis and crossing and selction	Examples additionally include genetic engineering e.g. gene insertion and genome editing	Claims cover both, GE and essentially biological processes	Claims explicitly cover viable cells	Claims explicitly cover food / harvest derived of (in addition to seeds)
	campestris							
41.	WO2020249798 Tomato plant resistant to Tobamo Virus	Vilmorin	X	X		X	X	X
42.	WO2020254655 Pepper maintain green colour	Vilmorin	X	X		X	X	X
43.	WO2020234426 Rice increased yield	Univ Nanjing Agricultural	X	X	Transgenesis	X	X	
44.	WO2020248971 Maize changed architecture	Agricultural Univ China	X	X	Transgenesis	X	X	X
45.	EP3718396 Inbred diploid potato line	Agricultural Genomics Inst (CN)	X		?	X	X	X
46.	WO2020239984 Gene for parthenogensis	Keygene		X	X	X	X	(X)
47.	WO2020255099 Rice hybrid	IRRI	X			X		X
48.	WO2020257882 producing seedless vine grapes	CSIRO	X		X (but only to demon-strate gene function)	X	X	X
49.	WO2020260890 increased water efficiency (wheat)	Uni Essex	X	X		X		X
50.	WO2020190631 Soybean with reduced antinutritional content	Arcadia	X	X		X		X

Lack of democratic and legal oversight

The rise of seed monopolies is being fueled by substantial deficiencies in legal and political oversight at the EPO: the EPO profits from a growing patent 'business' as it is funded by the fees for the examination and granting of patents. In addition, there is no independent international court to supervise EPO decision-making, it is not part of the EU, but an intergovernmental body with its own laws and regulations whose structures and oversight have not been updated since the 1970s.

The European Patent Organisation has 38 contracting states, including non-EU countries such as the United Kingdom, Switzerland and Turkey. The Administrative Council is a supervisory body composed of representatives from the 38 contracting states of the European Patent Organisation. The Administrative Council, although it is responsible for overseeing the work of the EPO, has a complete lack of transparency and does not allow the participation of civil society organisations such as *No Patents on Seeds!*. In contrast, industry is invited as an observer to Administrative Council meetings, with representatives from the lobby groups BusinessEurope and the European Patent Institute (epi)[21] present.

In the absence of transparency, democratic oversight and independent jurisprudence, the interests of stakeholders benefiting from patents have a major advantage. Plants and animals as well as their genetic constituents are considered to be a playing field for big business, regardless of the consequences for consumers, farmers and breeders, or our food safety and sovereignty, the environment, biodiversity and animal welfare.

As a result, the patent system no longer strikes a balance between the interests of society and the interests of the patent industry. It has turned living beings into patentable "inventions".

New problems arising from the EU Unitary Patent

The situation will become even more pressing for several European countries in the next few years, as soon as the 26 member states of the EU become part of what is called the Unitary Patent system. This new system simplifies the process of putting European patents into effect on a national level ('validation'). This means that the situation, e.g. in the Visegrad states (Czech Republic, Hungary, Poland and Slovakia) or Austria, Croatia and Slovenia, will change dramatically. So far, most patents on seeds granted by the EPO never came into effect (were not validated) in these countries. In future, patents granted by the EPO will automatically become valid in these countries, as soon as the company pays the fees.

In addition, civil society organisations as well as farmers and breeders will have very little recourse to defend their interests at the Unified Patent Court, which will take the final decisions. The high fees requested for appealing decisions made by the Unified Court will in practice, in many cases, prevent objections. The 'scare' factor for deterring breeders, gardeners and farmers from working with more recent plant varieties will become even stronger. In the longer-term, it will no longer be possible for smaller breeders and farmers to defend their interests against hundreds or thousands of patents, and will, in particular, lead to the demise of regional or national breeding enterprises.

While the implementation of the UP into German law was substantially delayed by a decision of the German Supreme Court in March 2020, many observers still expect the system to come into effect within the next few years.

21 https://patentepi.org/de/

Glossary

- Administrative Council: The Administrative Council represents the 38 Contracting States of the European Patent Convention (EPC), comprising all the member states of the European Union together with Albania, the former Yugoslav Republic of Macedonia, Iceland, Liechtenstein, Monaco, Norway, San Marino, Serbia, Switzerland and Turkey. The Administrative Council is a supervisory body responsible for overseeing the work of the EPO. The Administrative Council nominates the president of the EPO and can decide on the interpretation of the EPC and its so-called Implementing Regulations.
- Article 53 b: In Article 53b of the European Patent Convention on the "Exceptions to patentability" plants and animals are being excluded from patentability: "European patents shall not be granted in respect of: […] (b) plant or animal varieties or essentially biological processes for the production of plants or animals"
- Conference of the Contracting States: Article 172 of the European Patent Convention foresees the possibility of the Convention to be revised by a Conference of the Contracting States. The Conference can be prepared and convened by the Administrative Council. Revised texts can be adopted by a majority of three-quarters of the Contracting States.
- Enlarged Board of Appeal: The Enlarged Board of Appeal is the highest legal decision making body at the EPO: the Enlarged Board of Appeal does not decide on the granting of particular patents, but is responsible for legal matters of relevance and for examination and granting of patents in general.
- European Patent Convention: The European Patent Convention is the legal basis of the European Patent Organisation, signed in 1973 by its Contracting States. It contains as well the so-called Implementing Regulations.
- European Patent Office (EPO): The two main institutions within the European Patent Organisation (EPOorg) are the European Patent Office (EPO) and the Administrative Council. The EPO examines and grants patents filed by the applicants.
- European Patent Organisation (EPOrg): The EPOrg is an intergovernmental organisation on the basis of the European Patent Convention (EPC), signed in 1973. The EPOrg is not part of the European Union (EU), which means that EPO decisions are not under the jurisdiction of the European Court of Justice.
- Implementing Regulations: The Implementing Regulations are part of the European Patent Convention. In regards to the patentability of plants and animals, the last amendment of the Implementing Regulations has been adopted by the Administrative Council in June 2017 (Rule 27 and 28). The new rule 28 (2) of the Implementing Regulations clarifies: "Under Article 53(b), European patents shall not be granted in respect of plants or animals exclusively obtained by means of an essentially biological process."
- Plant Variety Protection System (PVP): The System of Plant Variety Protection of UPOV (International Union for the Protection of New Varieties of Plants) is an intellectual property right that gives breeders an exclusive right to the production and sale of new varieties over a period of 25 or 30 years. The protected varieties can be used by other breeders for the development of other new varieties ('breeders' exemption').
- Technical Board of Appeal: The Technical Board of Appeal is responsible for cases that are not decided in the first instance.
- Unitary Patent and Unified Patent Court: In future the EPO will be granting patents with a "unitary effect" under the so-called new "Unitary Patent". This will not change the way how patents are examined, but will ease the way to put the patents in force after being granted by the EPO. Currently it is planned, that 25 member states of EU will join (all besides Spain and Croatia). While the costs for the companies to get patent protection are lowered, the fees to challenge the patents in the Unified Patent Court are very high.