NO PATENTS ON SEEDS!

Stop patents on our food plants!

Research into patent applications conducted in 2020 shows how the industry is escaping prohibitions in patent law

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Executive summary

The problem:

Patents granted on seeds represent one of the biggest risks to global food security and regional food sovereignty. Patents create monopolies: plants and animals claimed in patents cannot 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 large 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. These developments will also have consequences for the Global South.

The ongoing controversy:

In June 2017, the European Patent Office (EPO) (↗ „Glossary“) decided that patents on conventionally bred plants and animals should no longer be granted. However, there are still legal loopholes: The EPO does not obey the profound differences between genetic engineering (patentable) and conventional breeding (not technical, not patentable). In current EPO practice, plants derived from random genetic changes are considered to be patentable inventions. There are already several examples showing how the legal loopholes have allowed the EPO to still grant patents, e.g. on beer and barley, melons and lettuce derived from random methods of conventional breeding.

The strategy of the big companies:

As shown in the overview of patent applications provided in this report, companies, such as BASF, Bayer-Monsanto, DowDupont (Corteva) or KWS seem actively trying to exploit these legal loopholes: The companies use specific wording in their patent applications to mix technical elements (genetic engineering) with standard methods of conventional breeding to give the impression of a technical invention. If these patents are not stopped, there will be huge implications for breeders, farmers and consumers, who are all becoming more and more dependent on big companies that can control access to biological resources needed for further breeding. Therefore, political decisions have to be taken as soon as possible – otherwise the ongoing legal uncertainty will undermine our global food security.

The political demand:

No Patents on Seeds! wants to achieve ‘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 patents.

Extended summary

Patents create monopolies: conventionally bred plants and animals claimed in patents cannot 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 large 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. These developments will also have consequences for the Global South. Therefore, patents granted on seeds must be considered to be one of the biggest risks to global food security and regional food sovereignty.

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

However, the decision did not go far enough. Specific reasons 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 patents on random genetic mutations. The wording of this document does not differentiate between spontaneously occurring gene variants and random mutations, on the one hand, and technical interventions generated through genetic engineering (including genome editing), on the other hand. Therefore, in current EPO practice, randomly mutated plants are considered to be patentable inventions. There are already several examples showing how the legal loopholes introduced by the Administrative Council have allowed the EPO to grant patents, e.g. on beer and barley, melons and lettuce derived from random methods of conventional breeding.

Previous decisions of the Enlarged Board of Appeal (both G2/07 and G1/08) make it 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 desired trait is achieved.

As shown in the overview of patent applications provided in this report, companies, such as BASF, Bayer-Monsanto, DowDupont (Corteva) or KWS seem actively trying 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 are seeming systematically to obscure the distinction between conventional breeding and genetic engineering. In these cases, all plants (or animals) with the characteristics described in the patent, are claimed as an invention. In most cases, additional elements are introduced as 'technical toppings' to simulate real inventions.

This industry strategy is a major cause of 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 from conventional breeding. This means that, even though they are not deemed patentable, they may still fall under the scope of a patent.

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

Furthermore, the research shows that within the last ten years, around 100 patent applications were filed each year in Europe for conventional plant breeding. From past experience with patents in the field of biotechnology, we can expect that around 30 to 50 percent of these patents will be granted. As data base research shows, some of these patents cover several dozen or even more than a hundred varieties.

According to recent decisions of the EPO (G3/19), the new Rule 28(2) will only be applied to patents filed after July 2017, and it might therefore take the EPO more than ten years to close the legal loopholes in further decision-making processes. Such a long period of time is needed in many cases before final decisions are made on patent applications. However, so far, no decision making has been started on patents filed since then, not a single relevant patent application had been granted or rejected by the end of 2020. Therefore, it can be expected that waiting for a final decision on relevant cases might prolong legal uncertainty for another ten years.

This means that hundreds more or even thousands of patent applications will be filed and many 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, there will be huge implications for breeders, farmers and consumers, who are all becoming more and more dependent on big companies that can control access to biological resources needed for further breeding. Therefore, political decisions have to be taken as soon as possible without waiting for the EPO to decide on a case by case basis.

If this does not happen, continued legal uncertainties, political controversies or ongoing legal challenges, could hamper or even disable plant breeding; at the same time, smaller breeders could see a loss in profitability. There could also be an impact on the future of food and agriculture as well as on livelihoods; these are risks that could be further intensified and escalated by ongoing climate change.

In its campaign, *No Patents on Seeds!* wants to continue to safeguard the '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 patents.

In addition, the 'freedom to operate' is the precondition for the future of

- Diversity in the fields,
- Farmers` rights,
- Choice for consumers and
- food security as well as food sovereignty.

Free the seeds! Save the future of our food!

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 which are genetically engineered.

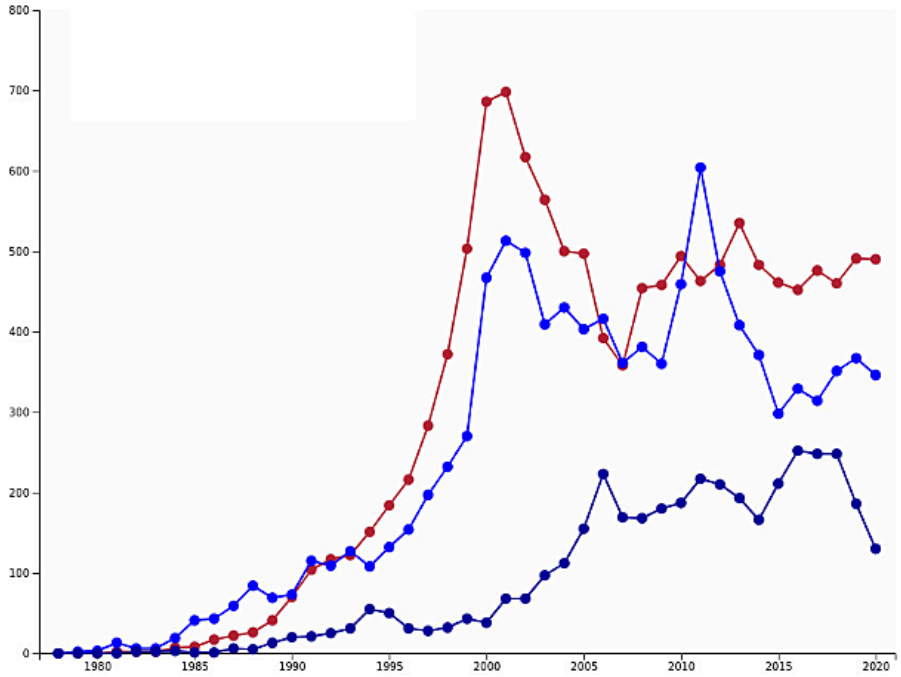

Figure 1: Patents on plants - number of patent applications for all plants under PCT/WIPO (upper line) and at the EPO (middle line) as well as patents on plants granted (lower line) by the EPO per year. Research according to official classifications (IPC A01H or C12N15/82). Source: www.kein-patent-auf-leben.de/patentdatenbank/

There is an alarming trend of patents being extended to conventional breeding: within the last ten years, around 100 new patent applications involving conventional plant breeding in Europe were filed each year (via EPO or WIPO). Out of more than 1000 patent applications, around 200 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) (↗ „Glossary"), 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 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 possibly more than a hundred of plant varieties.[2] Depending on the business strategy of the patent holder, licenses may be needed or access to biological resources may be blocked.

1 www.epo.org/law-practice/legal-texts/html/epc/2016/e/ar53.html
2 www.euroseeds.eu/pinto-patent-information-and-transparency-on-line/

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 cannot be used by other breeders, gardeners or farmers for further breeding unless they have permission from 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 development of new varieties. In many cases, the patents also cover the use of the harvested plants for food production. This is entirely contrary to the current plant variety protection system (PVP) (↗ „Glossary"), 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 the fact that patents on plant varieties are prohibited in Europe, the European patents granted on conventionally bred plants already cover 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). It is likely that in addition several other patents covering conventional breeding are not listed in the database and also not made accessible via license fees.

Table 1: Overview of 10 examples of European patents already granted that affect European 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 downy 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

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

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 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 mostly favour the larger companies (see figures 2 and 3).

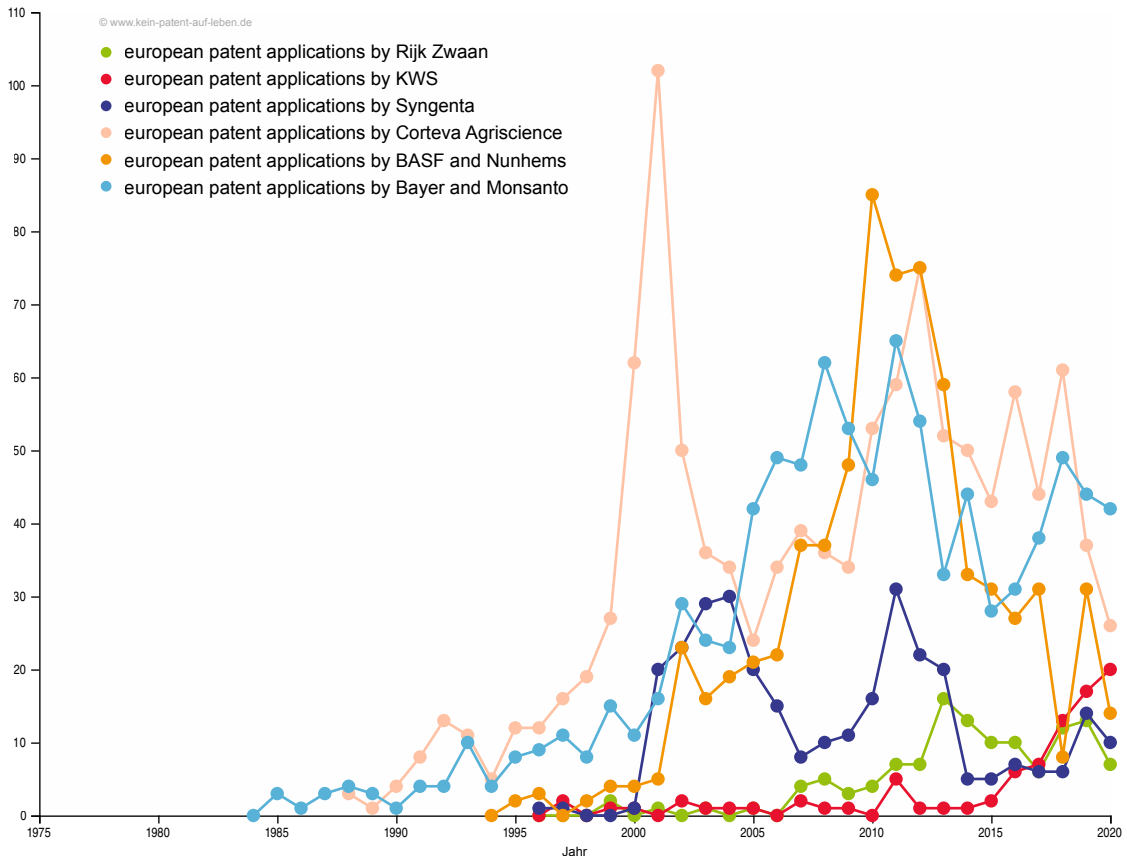

Figure 2: Patents on plants - number of patent applications for all plants under PCT/WIPO categorised by companies per year. Research according to official classifications (IPC A01H or C12N001582).
Source: www.kein-patent-auf-leben.de/patentdatenbank/

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

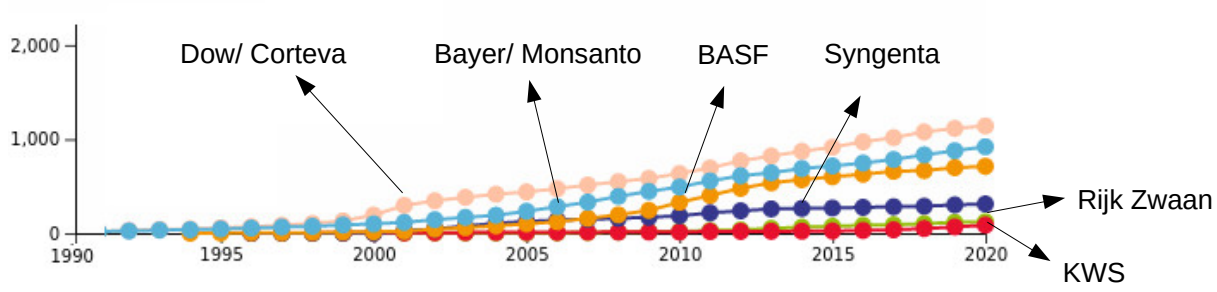

Figure 3: Patents on plants - number of patent applications for all plants under PCT/WIPO categorised by companies, per year, accumulated since 1990. Research according to official classifications (IPC A01H or C12N15/82).
Source: www.kein-patent-auf-leben.de/patentdatenbank/

The developments will also have consequences for the Global South, where many countries have adopted legislation to allow patents on seeds. Recent findings[5] 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 regional traditions of production, propagation and seed exchange.

From a global perspective, agro-biodiversity is one of the most important preconditions 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.

Some success for *No Patents on Seeds!*

No Patents on Seeds! was established 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', and, instead, 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 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. 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.

5 https://onlinelibrary.wiley.com/doi/full/10.1111/jwip.12143
6 https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1478769496064&uri=CELEX:52016XC1108(01)
7 Resolution 2012: https://www.europarl.europa.eu/doceo/document/TA-7-2012-0202_EN.html
Resolution 2015: https://www.europarl.europa.eu/doceo/document/TA-8-2015-0473_EN.html

New legal loopholes

However, the decision did not go far enough. A specific reason for concern: the Administrative Council based its decision on a proposal made by the previous President of the EPO that still allows patents on genetic variations ('mutations').[8] No differentiation is made between naturally occurring gene variants and random mutations, on the one hand, and technical interventions generated by genetic engineering, including new methods such as genome editing (e.g. CRISPR/ Cas gene scissor applications), on the other hand.

This legal loophole has far reaching consequences. Companies now use specific wording in their patents 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, additional 'technical toppings' such as genome editing or methods of transgenesis are introduced. Companies are systematically attempting to blur the distinction between conventional breeding and genetic engineering, as well as exploit the legal loopholes 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 a desired trait (breeding characteristics). 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, or directly generating 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) have been further heightened by the Nobel Prize being awarded in 2020 to two of the inventors of CRISPR/Cas.

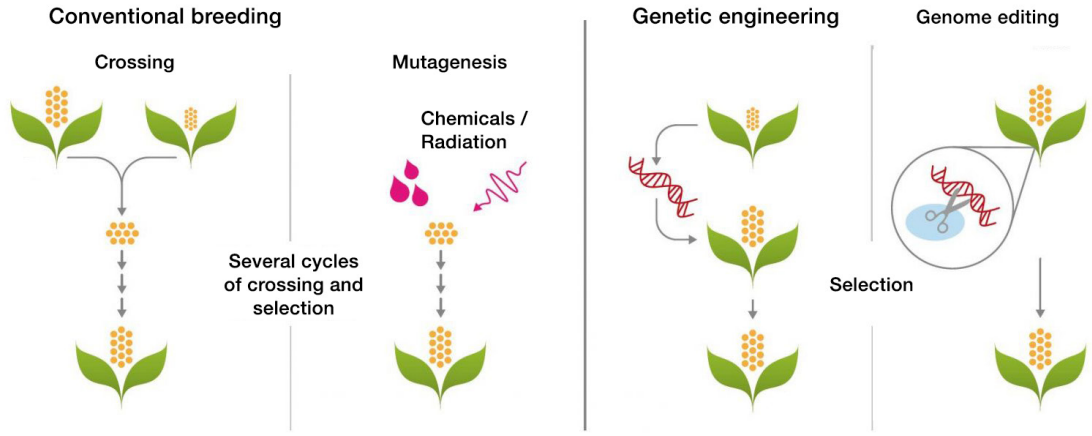

Figure 4: Differences between conventional breeding (including random mutagenesis) versus genetic engineering (including genome editing): conventional breeding always needs several cycles of crossing and selection to achieve to a desired trait, while GE can be used to directly insert new characteristics into a plant.[9]

8 www.epo.org/modules/epoweb/acdocument/epoweb2/256/en/CA-56-17_en.pdf

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

If this distinction is not established in patent law, breeders, gardeners and farmers will still be trapped by patents even if they do not use methods of genetic engineering, 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 on plants or animals after further crossing.

Research into filed patent applications covering conventional breeding 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 patent protection could become valid. 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, 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 of 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) and names of relevant companies, as well as on the analysis of the content of several hundred patent applications. During 2020, 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. Patent applications for non-food plants (such as ornamental plants, tabacco, hemp), or applications which were not clearly defined in their technical approach, were considered to be less relevant.

The 50 patent applications that were selected cover fruits, e.g. melons or grape vines, vegetables, e.g. spinach, broccoli, lettuce, pepper and tomatoes, and also cereals, e.g. wheat, rice, maize and as well soybean or oilseed rape.

The patents were filed by huge corporations, such as Bayer (Monsanto), BASF, DowDupont (Corteva), Syngenta (Chemchina), or 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.

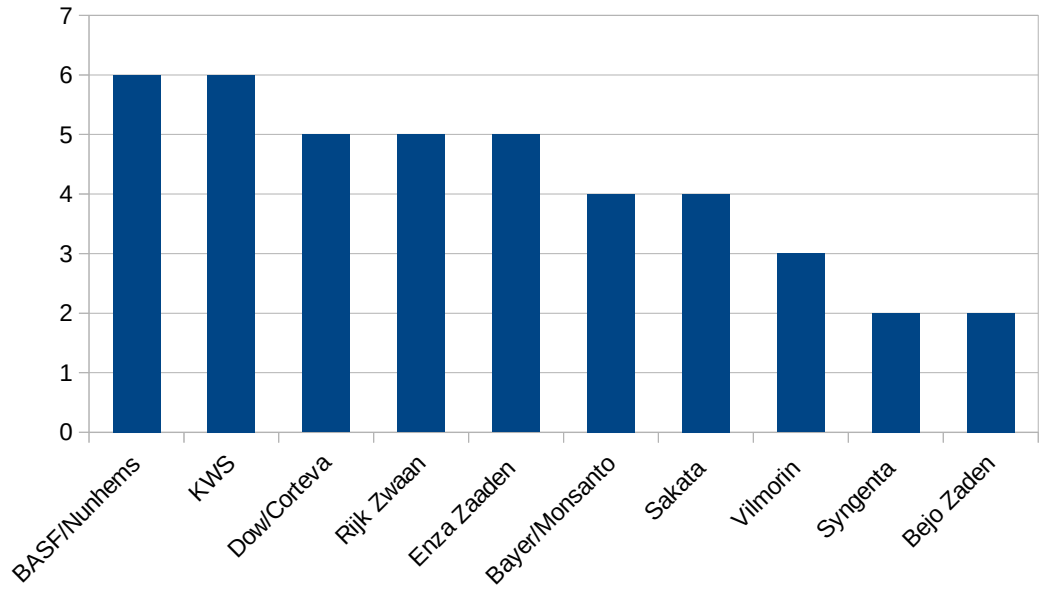

Figure 5: Companies with more than one patent application covering conventional plant breeding, published in 2020.

Five criteria were applied to categorise the patent applications:

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

There is evidence that the claims blur the distinction between conventional breeding and GE in more than 90% of cases, while GE was used additionally to establish the desired trait in only about 10% of cases. In more than 30% of cases, random mutagenesis was used together with crossing and selection. Explicit claims on cells were filed in more than 50% of cases. In around 60% of cases, the patents explicitly extended to the harvest and food derived thereof. These results are shown in Figure 6.

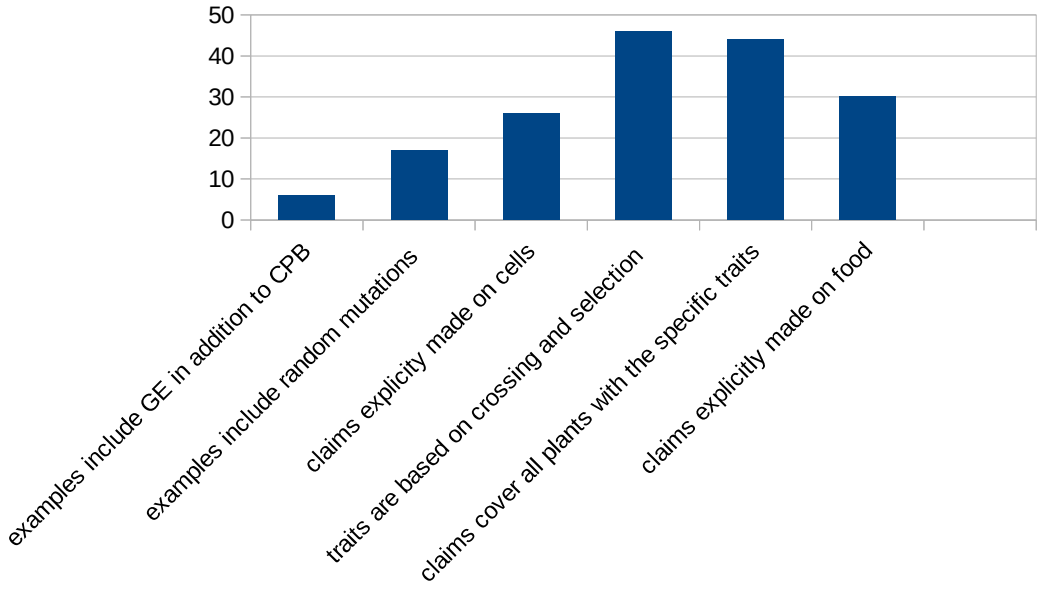

Figure 6: Analysis of 50 international patent applications covering food plants, published in 2020, designated to become European patents. There is evidence that, in most cases, the claims are directed to all plants inheriting specific traits (breeding characteristics), no matter how they were achieved.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

The analysis shows to which extent the companies are attempting to exploit the loopholes in current prohibitions introduced by documents adopted by the Administrative Council (CA/56/17, CA/PL 4/17 and CA/PL 4/20). There is evidence 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 achieving 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 will hundreds of conventionally bred varieties be affected by European patents, but, in many cases, also the food derived thereof.

Case study: How companies are attempting 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 is actively looking to exploit these legal loopholes. In most cases, additional elements are introduced as 'technical toppings'.

Evidence of this can be found by comparing the description of the patent applications ("examples") with the wording of the claims: out of 50 relevant patent applications covering conventional plant breeding (CPB) filed 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 was it shown to be '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 cover 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. The patent applications aim to escape the prohibitions in patent law on conventional breeding; they exploit loopholes established through the decision-making of the Administrative Council of the EPO, such as random mutagenesis. As a result, the patent can be granted even if the plants are derived from random processes and based on several cycles of crossing and selection to achieve the desired traits. This problem is exemplified in the following case study on patent application WO2020239495 filed by BASF/ Nunhems.

Case study - Patent application WO2020239495 filed by BASF/ Nunhems: Exploring the patent strategy

Patent applications, such as WO2020239495 filed by BASF/ Nunhems on 'oomycete resistance in tomato and cucumber', are typical for this kind of application. Oomycetes are known to cause plant diseases such as downy mildew and late blight.

In short

- The examples in the patent begin with seeds and plants with known resistance to oomycetes, originally collected in India and obtained from a US gene bank. These plants were subsequently used for further crossing and selection. Additional gene analysis (genotyping) was performed and pest infestation was tested (phenotyping) by exposing the plants to oomycetes. Random mutagenesis methods are then used to achieve further relevant gene variants. This is followed by further crossing and selection to establish the intended trait. Therefore, the trait as described is based on crossing and selection, with and without random mutagenesis. A targeted method to directly introduce a trait via genetic engineering (including genome editing) was not used.
- The claims are not restricted to any method; the claims cover all plants inheriting the traits and characteristics as described. Crossing and selection is not mentioned in the claims. Instead, the methods which are explicitly mentioned refer to the legal loopholes created by the document published by the Administrative Council (CA/56/17): Claims 7 and 17 are directed to plants derived from random mutagenesis, genome editing or generated from cell cultures.

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

According to the examples, the following steps in 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 by 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 whether 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 mutagens, followed by further selec tion (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 that 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.
- Claim 3 is directed to tomato plants with reduced susceptibility to *Phytophthora infestans* and *homozygous alleles* as described.
- 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 created by the documents 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 of the plants, 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 mention 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*") refer to the loopholes created by the documents published by the Administrative Council (CA/56/17). If the patent is granted as set out in the application, it will cover all plants, seeds and fruits, also those derived from random processes, including conventional breeding and selection.

Before the patent is granted, it is likely that a disclaimer will 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 a gene bank. However, this would not substantially alter the scope of the patent, as long as plants derived from random mutagenesis are regarded as technical (patentable) inventions. With current EPO practice, such a disclaimer would exclude just those plants as derived from the gene bank. However, these plants should not be regarded as new or inventive and not be covered by the patent anyway.

There is already proof that the legal loopholes introduced by the Administrative Council continued to allow the EPO to grant patents or reject oppositions after June 2017, e.g. on beer and barley[10], melons[11] and lettuce[12] derived from methods of conventional breeding.

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

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 an 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 temperatures	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 prioritising the granting of patents to Dutch companies in this period of time. The EPO could have adopted this policy to raise awareness that not only big international companies are interested in being granted such patents. However, in the same period of time, most patent applications in conventional plant breeding were filed by BAYER (Monsanto/ Seminis) see: https://www.no-patents-on-seeds.org/en/news/report2020.**

In the second half of 2019 and in 2020, hardly any further patents were granted on conventionally bred plants; this was due to unresolved legal questions regarding decision G3/19. However, this moratorium ended in June 2020 and, in 2021, as the most recent files of patent examinations show, the EPO is ready to grant further patents on plants with traits derived from non-technical processes.

The legal situation

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

- 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 plant and animal breeding (non-patentable) to distinguish them from technical inventions (patentable). It came up with some rather ambiguous wording explaining 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 EPO decision-making. With the different breeding categories as explained above (Figure 4) in mind, 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 purposefully 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[13], which concludes that only methods of genetic engineering that directly intervene in the genome of plants and animals are regarded as patentable. The EU Parliament[14] and the Administrative Council of the EPO Member States[15] take the same view.

However, in preparation for the implementation of Rule 28(2) decision in June 2017, the Administrative Council adopted a document (CA/56/17)[16] which contradicts 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 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 documents are now driving current decision-making at the EPO by opening up the loopholes which are being exploited by industry as shown in Figure 5.

From a purely legal perspective, the G2/07 and G1/08 decisions are the final decisive documents which should

13 http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52016XC1108(01)
14 Resolution 2012: https://www.europarl.europa.eu/doceo/document/TA-7-2012-0202_EN.html
Resolution 2015: https://www.europarl.europa.eu/doceo/document/TA-8-2015-0473_EN.html
15 www.epo.org/news-issues/news/2017/20170629.html
16 www.epo.org/modules/epoweb/acdocument/epoweb2/256/en/CA-56-17_en.pdf

overrule the documents published by the Administrative Council (such as CA/56/17). Therefore, the contradictions that have emerged between the documents might be resolved in further case law and patent oppositions. However, according to another decision of the Enlarged Board of Appeal (G3/19), Rule 28(2) only needs to be applied to patents filed after July 2017.

No decisions have been taken on any of the filed applications since then, not a single relevant patent application had been granted or rejected by the end of 2020. Therefore, we can expect to wait for a final decision on relevant cases - with the associated prolongation of legal uncertainty - for another ten years. This uncertainty is further underscored in the new Guidelines for Examination, which came into force on 1 March 2021. In Chapter G, these guidelines appear to aim for a compromise between the different documents. But the actual wording only adds to the confusion and fails to bring further clarification.[17] It appears that the EPO, by providing some examples, is trying to introduce the idea that some plants derived from mutagenesis are still patentable, while others are not: "*A mutant of a plant carrying a heritable exchange in a nucleotide sequence effected by technical means, e.g. UV mutagenesis or CRISPR/Cas with the proviso that the plant is not exclusively obtained by means of an essentially biological process (EBP).*"[18] Currently, it is still unclear how such examples might bring about greater legal clarity and certainty.

This means that hundreds more patent applications will be filed, and many of these patents could be granted before sufficient legal clarity is achieved. In the light of the legal analysis provided and the history of the decision in regard to Rule 28(2), this would be unacceptable to traditional breeders, farmers, patent applicants as well as to *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 see their businesses become increasingly unprofitable. The future of food and agriculture, as well as our livelihoods could be impacted, all of which could be intensified and escalated by the risks associated with ongoing climate change.

2. Definition of products used in or derived from breeding

Furthermore, as regards Rule 28(2) and the document adopted by the Administrative Council (CA/56/17), more clarification is needed on paragraph 51 of the submission made by the former President. This 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 no justification for introducing such a specific exemption, which may render the effects of Rule 28(2) ineffective in many cases.

This problem is acknowledged in the new Guidelines for Examination. In Chapter G, the guidelines state 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 all relevant breeding materials, including viable cells, are excluded under Article 53(b) and Rule 28(2).

17 https://www.epo.org/law-practice/legal-texts/guidelines.html
18 Part G – Chapter II-41, 5.4.2.1; Examples
19 https://www.epo.org/law-practice/legal-texts/guidelines.html

3. Limiting the scope of protection

As evidence presented in Figure 4 shows, the current strategy of companies filing patents on conventional breeding, is based on blurring the differences between GE and conventional plant breeding by adding technical toppings and claiming all plants with specific traits (breeding characteristics). There is also evidence in the patent applications of genome editing; this strategy is being followed in the opposite direction. In several cases, patent claims in patents filed on plants derived from GE techniques (involving, for example CRISPR/Cas) are extended to plants or animals, which may have the 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 rape

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 may still fall under the scope of a patent.

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

Therefore, we request the Administrative Council to develop other solutions, taking into consideration 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 clause 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 *No Patents on Seeds!* (2018) report.[20]

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

Now is the time to act!

In the last ten years, around 100 patent applications filed on plants were identified each year for conventionally bred plants. It can be expected that around 30 to 50 percent of these patents will be granted. As research in databases shows, some of these patents may seek to cover several hundred varieties.

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

Due to legal uncertainties, political controversies or ongoing legal cases, plant breeding might be hampered or even disabled. In particular, smaller breeders might see their business become much less profitable. The future of food and agriculture and our livelihoods could be impacted, and such risks could be intensified and escalated 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" that enables a patent on a plant or animal derived from a technical process to be extended to all conventionally bred plants with the same traits.

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

If this is not feasible, a change in the EPC can be decided by a Conference of the Contracting States (↗ „Glossary"). This conference has the power to change the text of the EPC if there is a majority vote to introduce stronger wording for the exclusion of plants and animals from 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 great care and decisiveness to overcome strong lobbying from the biotech industry and patent lobbyists to finally close all legal loopholes.

Annex

Tabled overview of 50 most relevant patent applications

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

	Patent number Plant species Trait Specials	Examples are based on crossing and selection	Examples combine random mutagenesis and crossing and selection	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	X	X		X		X
2	WO2020120242 Pepper (Solanacea) seedless	X	X		X	X	X
3	WO2020168166 clubroot resistant Brassica plants	X		(transgenic approach failed)	X		
4	WO2020239496 Downy mildew resistance in Cucurbitaceae	X	X		X	X	X
5	WO2020239495 oomycete resistance in tomato and cucumber	X	X		X	X	X
6	WO2020249593 Tomato improved ripening	X	X		X		X
7	WO2020006044 male sterility system	X			X	(X)	X
8	WO2020006112 similar as above	X			X	(X)	X
9	WO2020132188 maize (sweet corn) with resistance to Northern leaf blight	X			X	(X)	(X)
10	EP3701791 pepper fruits comprising two different colors	X					X
11	WO2020036950 canola (oilseed rape) with blackleg resistance	X			X		
12	WO2020036954 canola (oilseed rape) with blackleg resistance	X			X		

	Patent number Plant species Trait Specials	Examples are based on crossing and selection	Examples combine random mutagenesis and crossing and selection	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)
13	WO2020056259 hybrid breeding in wheat and others	X		X (CRISPR)	X	X	
14	WO2020139756 cotton resistant to Fusarium	X			X		
15	WO2020257273 pod shatter tolerant phenotype in Brassica	X					
16	WO2020051166 traits of tolerance under water stressed conditions	X			X		
17	WO2020078852 tomato with modified sugar content	X			(X)		X
18	WO2020008078 modifying tuber shape of a potato	??		X	X		
19	WO2020064687 glyphosate resistant beta vulgaris, sugar beet		X				
20	WO2020157197 haploid inducer Brassica, Sorghum Helianthus	X	X		X		
21	EP3718397 Wheat cytoplasmic male sterility restorer genes	X		X (but only to demonstrate gene function)	X	X	
22	WO2020229533 Drought tolerance in maize	X	X	X	X only methods for producing		
23	WO2020239680 haploid inducer maize, sorghum	X			X	X	

	Patent number Plant species Trait Specials	Examples are based on crossing and selection	Examples combine random mutagenesis and crossing and selection	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)
24	WO2020025631 resistance to Cucurbit Yellow Stunting Disorder virus (CYSDV) in plants of the Cucurbitaceae	X		Only mentioned as possibility (also random mutagenesis)	X	X	X
25	WO2020025632 Mutant allele leading to only male flowers in cucumber plant	X			X	X	
26	EP3650463 Reversible genetic male sterility in Latuca, lettuce, endive, cichorium	X (also crossing via bumble bees)			X		
27	WO2020128044 Spinach with resistance to Peronospora farinosa	X			X	X	X
28	WO2020193712 Brassica plants with resistance to downy mildew	X			X	X	X
29	WO2020035145 lettuce with resistance to downy mildew	X		X (but only to demonstrate gene function)	X		X
30	WO2020126500 lettuce with resistance to downy mildew	X		X (but only to demonstrate gene function)	X		X
31	WO2020125925 iceberg lettuce easier to harvest	X				X	X
32	WO2020148021 Tomato with resistance to Tobamo virus	X		X (but only to demonstrate gene function)	X	X	X
33	WO2020239186 Melons with resistance to downy mildew	X	X		X	X	X
34	WO2020099330 Potato with resistance to Phytophthora infestans	X				Plants derived from vegetative propagation	

	Patent number Plant species Trait Specials	Examples are based on crossing and selection	Examples combine random mutagenesis and crossing and selection	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)
35	WO2020239215 spinach with resistance to downy mildew	X			X	X	X
36	WO2020077224 pepper plants with resistance against fusarium	X			X	X	X
37	EP3682732 downy mildew resistant cabbage	X			X		X
38	EP3721705 producing Lactuca plant seeds using megachile bees	X (via pollination with bees, but only the process)					
39	EP3756454 Hybrid production in broccoli	X			X		X
40	WO2020030804 Cauliflower resistance to Xanthomonas campestris	X	X		X	X	X
41	WO2020249798 Tomato plant resistant to Tobamo Virus	X	X		X	X	X
42	WO2020254655 Pepper maintain green colour	X	X		X	X	X
43	WO2020234426 Rice increased yield	X	X	Transgenesis	X	X	
44	WO2020248971 Maize changed architecture	X	X	Transgenesis	X	X	X
45	EP3718396 Inbred diploid potato line	X		?	X	X	X
46	WO2020239984 Gene for parthenogenesis		X	X	X	X	(X)
47	WO2020255099 Rice hybrid	X			X		X

	Patent number Plant species Trait Specials	Examples are based on crossing and selection	Examples combine random mutagenesis and crossing and selection	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)
48	WO2020257882 producing seedless vine grapes	X		X (but only to demonstrate gene function)	X	X	X
49	WO2020260890 increased water efficiency (wheat)	X	X		X		X
50	WO2020190631 Soybean with reduced antinutritional content	X	X		X		X

The 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 (↗ „Glossary") 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[21] and the European Patent Institute (epi)[22] present.

In the absence of transparency, democratic oversight and independent jurisprudence, 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 or 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".

21 www.businesseurope.eu/
22 https://patentepi.org/en/

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 most of the 27 member states of the EU become part of what is called the Unitary Patent (UP) (↗ „Glossary“) 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 have never come into effect (were not validated) in these countries. In future, Unitary 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 UP Court, which will take the final decisions. The high fees requested for appealing decisions made by the UP 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.

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 53(b) of the European Patent Convention on the "Exceptions to patentability" plants and animals are 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 being 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 three-quarter majority 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 also contains 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 based on 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 was 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 that patents are examined, but will ease enforcement after they are granted by the EPO. Currently it is planned, that 25 member states of EU will join (all except Spain and Croatia). Whereas the costs for the companies to obtain patent protection were reduced, the fees to challenge the patents in the Unified Patent Court are very high.

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