NO PATENTS ON SEEDS!



Eleven reasons why Europe needs to ban patents on food plants and farm animals

New applications for patents on conventional plant and animal breeding

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Eleven reasons why Europe needs to ban patents on food plants and farm animals

New applications for patents on conventional plant and animal breeding

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Summary

The problem

Patents create monopolies: conventionally bred plants and animals claimed in patents may 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.

In contrast to European practice under the plant variety protection system (PVP) (↗ Glossary), access to biodiversity needed for the further breeding of food plants and livestock can be controlled, hampered and even blocked by patent holders. At the same time, the large agrochemical companies (such as Bayer) file significantly more plant patents per year than any of the traditional breeders. As experience shows, the dynamics within the patent regimes mostly benefit the larger companies.

In the end, a handful of large corporations may 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 developments will also have consequences for the Global South. Against this backdrop, patents on seeds must be seen as one of the biggest risks to global and regional food security and sovereignty.

The report

The report gives an overview of patent applications filed for conventional plant and animal breeding between 2018 and 2019, which may be granted by the European Patent Office in the next few years.

To determine which plants and animals were derived from conventional breeding, we investigated whether the methods used in the breeding process directly targeted the genome, with the aim of inserting additional genes or modifying the genome for a desired trait. These processes were considered to be genetic engineering. In contrast, conventional breeding starts from a broad range of biodiversity. The desired characteristics are the outcome of crossing and selection. Such processes were considered to be non-technical or "essentially biological". The wording of European patent law prohibits the patenting of non-technical breeding.

From the beginning of 2018 until the end of 2019, around 450 patent applications were filed for plants and plant breeding, with more than 100 patents covering conventional breeding. Our research found that around 70 patents on plants and plant breeding were the most relevant for this report. These were therefore examined in more detail.

Most patents were for breeding melons, followed by spinach, maize and tomatoes. Other patents cover alliums, artichokes, eggplants, bananas, basil, beet, broccoli, cassava, cauliflower, celery, cotton, endive, potatoes and rice.

In addition, we carried out a more detailed examination of ten patent applications claiming livestock. These examples covered species such as cattle, pigs, sheep, horses, goats, rabbits and poultry.

Eleven examples

The report contains eleven examples to highlight the legal loopholes used by the companies to escape the prohibitions in patent law and the monopoly claims they can acquire.

1. Patent application WO2019121603 covers all cassava and manioc plants (Manihot esculanta) which undergo chemical mutagenesis, regardless of which biological characteristics are ultimately achieved.
2. The company Kleinwanzlebener Saatzucht (KWS) claims around 80 plant species resistant to a fungal disease, i.e. northern corn leaf blight (EP3447135), that occurs, e.g. in maize.
3. The Dutch breeder Rijk Zwaan claims endive plants (Cichorium endivia L.) which are non-browning after being brought into contact with warm water (EP3427575).
4. The company Carlsberg, one of the largest breweries in the world, was heavily criticised in public for three 'patents on beer'. Now, the company has once again has filed three patent applications on seeds, plants and resulting beverages, such as beer, as their 'invention' (WO2019129736, WO2019129739, WO2019134962).
5. Together with its vegetable breeding company, Seminis, Monsanto (Bayer) filed a patent claiming muskmelons (Cucumis melo) with red flesh (WO2019040455).
6. Bayer filed a patent application for cereal plants derived from plantlets stored in a liquid at a low temperature for several weeks (WO2019001793). Surprisingly, these plants showed a higher yield after planting.
7. The University of California applied for a patent on pepper plants (Capiscum annuum) with a "low destemming force" which means the peppers can be harvested more easily (WO2019191675). The plants were originally collected in Mexico and subsequently crossed with varieties marketed in New Mexico (USA).
8. BASF claims downy mildew-resistant (a fungal plant disease) basil plants (Ocimum basilicum) (WO2019068647). Wild plants were found to show resistance to downy mildew and were subsequently crossed with commercially traded varieties.
9. The Livestock Improvement Corporation Limited (New Zealand) has laid claim to a patent on breeding dairy cows based on analyses of a specific gene (WO2019125187). The company identified variants of a naturally occurring gene that is supposed to influence the amount of milk a dairy cow produces.
10. The French company Genes Diffusion uses a technical device and a fluorescent marker to select sperm cells according to the expected sex of the offspring (EP3570978). The company not only claims the technical process but also the selected sperm cells as its 'invention'.
11. The US company Inguran is trying to obtain a patent on using embryos of mammalian species for the extraction of cells (gametes, such as oocytes and sperm cells) to be used in further breeding (WO2019100018). This would mean that several generations can be created without involving adult animals as well as speeding up breeding.

New legal loopholes and some legal chaos

In June 2017, the Administrative Council (↗ Glossary) of the EPO decided that patents on conventionally bred plants and animals should no longer be granted. 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!*.

However, the decision did not go far enough. Significantly, the Administrative Council based its decision on a proposal made by the previous President of the EPO that still allowed for patents on genetic variations ('mutations'). 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. Companies now use specific wording in their patents 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.

As shown in the overview of patent applications highlighted in this report, there is no doubt that the biotech industry is actively trying its utmost to exploit these legal loopholes. In most cases, additional elements are introduced as 'technical toppings' to simulate real inventions. There is already proof that the legal loopholes introduced by the Administrative Council allowed the EPO to grant such patents after 2017, e.g. on beer and barley, melons and lettuce derived from methods of conventional breeding.

This legal uncertainty turned into real legal chaos when, at the end of 2018, the Technical Board of Appeal (↗ Glossary) of the EPO ruled in its decision T1063/18, which is binding for all patent examiners at the EPO, that the decision of the Administrative Council should no longer be applied. This development returns us to the absurd situation prior to 2017: while processes for conventional breeding are regarded as non-patentable, the resulting plants and animals are nevertheless considered to be 'inventions' and are patentable. By applying this legal interpretation, the exclusion of "essentially biological" breeding in European patent law becomes meaningless.

The decision is also in total contradiction to the political will and democratic decision-making of the Administrative Council and the contracting states of the EPO.

Free the seeds!

In its 2020 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 patents.

1. Introduction

'Patents on life' claiming plants and animals as 'inventions' first emerged in Europe in the1980s 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) (↗ Glossary), 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 3700 patents on plants and nearly 2000 patents on animals have been granted in Europe, most of them genetically engineered.

Patents create monopolies: plants and animals claimed in patents may 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. 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.

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) comprises thirty-eight member states, including non-EU countries such as the United Kingdom, Switzerland and Turkey. The Administrative Council (↗ Glossary) is a supervisory body composed of representatives from the thirty-eight 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)[2] (↗ Glossary) present.

In the absence of transparency, democratic oversight and independent jurisprudence, the interests of stakeholders benefitting 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".

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

2. The controversy over patents on conventional plant and animal breeding

No Patents on Seeds! was initiated as a European coalition in 2007, with the aim of stopping patents from being granted on conventional plant and animal breeding. 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.

Success for the opposition to 'patents on seeds'

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) (↗ Glossary), which prohibits patents on 'essentially biological' breeding (Art 53 b). The decision of the Administrative Council to change the Implementing Regulations (↗ Glossary) of the EPC 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[3], the EU Parliament[4] and the Council of the EU Member States[5].

New legal loopholes

However, the decision did not go far enough. Significantly, the Administrative Council based its decision on a proposal made by the previous President of the EPO that still allowed for patents on genetic variations ('mutations').[6] 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 had far reaching consequences. Companies now use specific wording in their patents to mix technical elements (such as CRISPR/ Cas applications) with standard methods of conventional breeding: (i) If random mutagenesis is performed as a starting point, followed by crossing and selection to establish desired traits, it is claimed that the random processes are 'technical' and 'inventive'. Based on these random processes, seeds, plants and harvested food are claimed as 'inventions'; (ii) Even if only crossing and selection (of the phenotype) was needed to achieve the desired characteristics, in many cases, random mutations are performed additionally. We call this a 'technical topping', and it is a way of exploiting the legal loophole introduced by the Administrative Council; (iii) Likewise, in several cases, methods of genetic engineering are mentioned which could be used to achieve similar results. Companies thereby systematically try to blur 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.

3 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52016XC1108(01)
4 https://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P7-TA-2012-0202+0+DOC+XML+V0//EN and https://www.europarl.europa.eu/doceo/document/TA-8-2015-0473_EN.html?redirect
5 www.epo.org/news-issues/news/2017/20170629.html
6 https://www.epo.org/modules/epoweb/acdocument/epoweb2/256/en/CA-56-17_en.pdf (Download PDF)

As shown in the overview of patent applications provided in this report, there is no doubt that the biotech industry is actively trying its utmost to exploit these legal loopholes. In most cases, additional elements are introduced as 'technical toppings' to simulate real inventions. There is already proof that the legal loopholes introduced by the Administrative Council still allowed the EPO to grant such patents after 2017, e.g. on beer and barley7, melons8 and lettuce9 derived from methods of conventional breeding.

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, followed by further crossing and selection. 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.[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.

New problems created by the EPO

This legal uncertainty turned into real legal chaos when, at the end of 2018, the Technical Board of Appeal (↗ Glossary) of the EPO ruled in its decision T1063/18, which is bindinsg for all patent examiners at the EPO, that the decision of the Administrative Council should no longer be applied. This development returns us to the absurd situation prior to 2017: while processes for conventional breeding are regarded as non-patentable, the resulting plants and animals are nevertheless considered to be 'inventions' and are patentable. By applying this legal interpretation, the exclusion of "essentially biological" breeding in European patent law becomes meaningless. The decision is also in total contradiction to the political will and democratic decision-making of the Administrative Council and the contracting states of the EPO.

In response, the President of the EPO, at the beginning of 2019, stayed all further patent procedures in the field of conventional breeding of plants and animals. In addition, he requested the highest legal institution of the EPO, the so-called Enlarged Board of Appeal (↗ Glossary) to assess the decision of the Technical Board of Appeal. The Enlarged Board of Appeal is expected to make its decision (G3/19) in the first half of 2020.

7 https://www.no-patents-on-seeds.org/en/patent-cases/beer
8 https://www.no-patents-on-seeds.org/en/patent-cases/melon
9 https://www.no-patents-on-seeds.org/en/node/589
10 See also the statement of the EU Commission:
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52016XC1108%2801%29

Table 1: Overview on activities at the EPO since the decision of the Administrative Council

June 2017	Administrative Council decides to change Rules 27 and 28[11] of the Implementing Regulations of the EPC.
January 2018	EPO grants a patent on a melon[12] (EP 2455475) based on conventional breeding to the Dutch company ENZA Zaden.
June 2018	EPO grants a patent on lettuce[13] (EP2966992) based on conventional breeding to the Dutch company Rijk Zwaan Zaadteelt.
September 2018	Monsanto's patent on 'severed broccoli'[14] (EP1597965) based on conventional breeding is revoked after an opposition by *No Patents on Seeds!* and other organisations.
October 2018	EPO rejects opposition filed by *No Patents on Seeds!* against patents on barley and beer[15] (EP2384110 and EP2373154).
October 2018	EPO grants a patent on salmon and trout[16] (EP1965658) based on conventional breeding.
December 2018	The Technical Board of Appeal of the EPO decides that the changes in the Implementing Regulations off June 2017 are not to be applied (T1063/18).
December 2018	Monsanto announces it will appeal the decision on the 'severed broccoli'[17].
April 2019	The President of the EPO stays all proceedings[18] in regard to "essentially biological processes" and refers two questions[19] (case G3/19) to the Enlarged Board of Appeal.
September 2019	The European Parliament publishes a resolution[20] in regard to case G3/19.
October 2019	By October 2019, several official bodies, organisations and *No Patents on Seeds!* had filed official statements[21] in regard to case G3/19.
April-June 2020	The Enlarged Board of Appeal is expected to take a decision (G3/19).

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 25 member states of the EU become part of what is called the Unitary Patent (↗ Glossary) system. This new system simplifies the process of putting ('validation') European patents into effect on a national level. 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.

11 https://www.epo.org/law-practice/legal-texts/official-journal/2017/07/a56.html
12 https://www.no-patents-on-seeds.org/en/node/459
13 https://www.no-patents-on-seeds.org/en/node/589
14 https://www.no-patents-on-seeds.org/en/patent-cases/severed-broccoli
15 https://www.no-patents-on-seeds.org/en/patent-cases/beer
16 https://www.no-patents-on-seeds.org/en/node/578
17 https://www.no-patents-on-seeds.org/en/patent-cases/severed-broccoli
18 https://www.epo.org/law-practice/legal-texts/official-journal/information-epo/archive/20190410.html
19 https://www.epo.org/law-practice/legal-texts/official-journal/2019/04/a34/2019-a34.pdf
20 https://www.europarl.europa.eu/doceo/document/B-9-2019-0040_EN.html
21 https://www.epo.org/law-practice/case-law-appeals/eba/pending/g3-19.html

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 (↗ Glossary), 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.

3. Political decisions to be taken in 2020

There are fundamental decisions that need to be taken by the Administrative Council representing the member states of the EPC as soon as the Enlarged Board of Appeal has published its decision: to put an end to the uncertainty and the legal chaos surrounding EPO decision-making, the European governments have to either specify the rules for interpretation of the EPC or change the EPC itself.

- The (legally binding) rules for the interpretation of the EPC are set out in the so-called Implementing Regulations (↗ Glossary). These regulations can be changed by a two-thirds majority of the 38 member states of the Administrative Council, as was the case in 2017. Each member state has one vote.
- Another way of changing the rules is to call a Conference of the Contracting States (↗ Glossary). 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. There is also a small possibility that the Administrative Council could change the wording of the EPC. However, this is only possible if all contracting states agree on such a process.

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.

This report provides an overview of the demands of *No Patents on Seeds!* that need to be fulfilled to establish legal clarity.[22]

22 For more information see statement in regard to case G3/19: https://www.no-patents-on-seeds.org/en/node/609

4. The *No Patents on Seeds!* mission

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.[23] 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 developments will also have consequences for the Global South, where many countries have adopted legislation to allow patents on seeds. Recent findings[24] indicate that 60% of the 126 countries in the Global South for which data were available, are ready to allow the patenting of 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.

Free the seeds!

In its 2020 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.

23 See also: https://etcgroup.org/sites/www.etcgroup.org/files/files/etc_platetechtonics_a4_nov2019_web.pdf
24 https://onlinelibrary.wiley.com/doi/full/10.1111/jwip.12143

5. Overview: some statistics on patents

At present, in Europe, an increasing number of patent applications are being filed on plants and animals. Around 3700 patents on plants have already been granted – most of them covering genetic engineering.

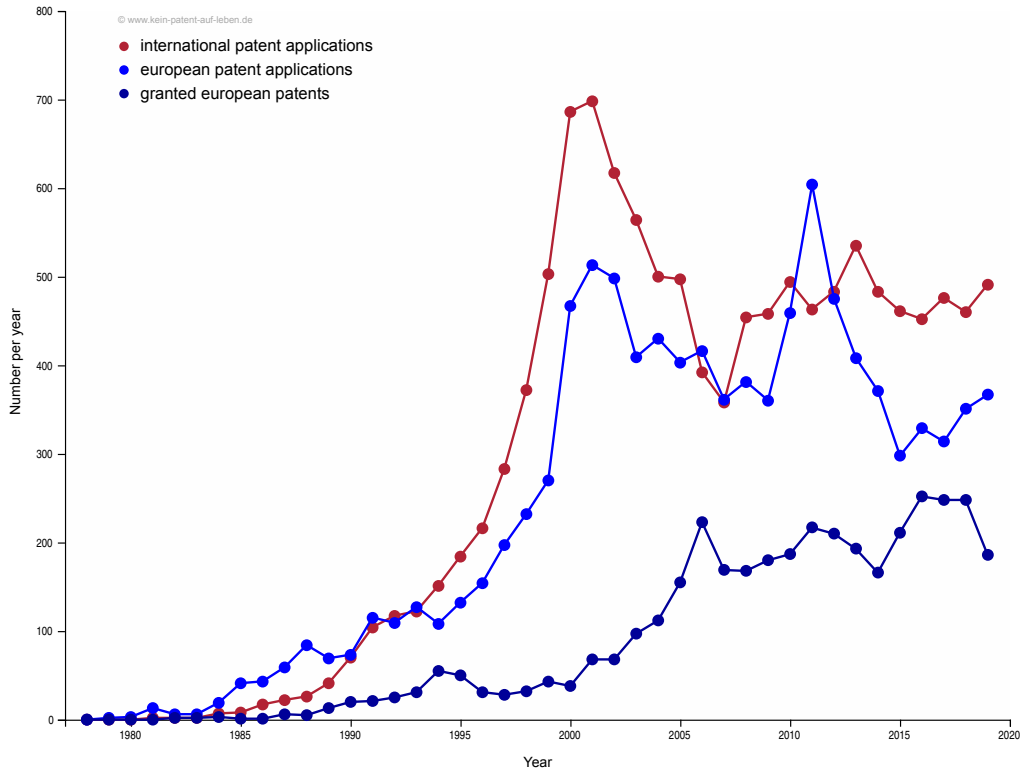


Figure 1: Patents on plants - number of patent applications for all plants under PCT/WIPO and at the EPO as well as of patents on plants granted by the EPO per year. Research according to official classifications (IPC A01H or C12N001582). Source: www.kein-patent-auf-leben.de/patentdatenbank/

In the last 10 to 15 years, there has been a steady rise in the number of patent applications being filed on plants derived from conventional breeding, i.e. not genetically engineered. More than 1600 such applications have been filed and around 220 patents have been granted to date. 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.

Every patent on conventionally derived traits can simultaneously impact the breeding of dozens or even hundreds of plant varieties.[25] 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.

25 See table 2 or https://www.euroseeds.eu/pinto-patent-information-and-transparency-on-line/

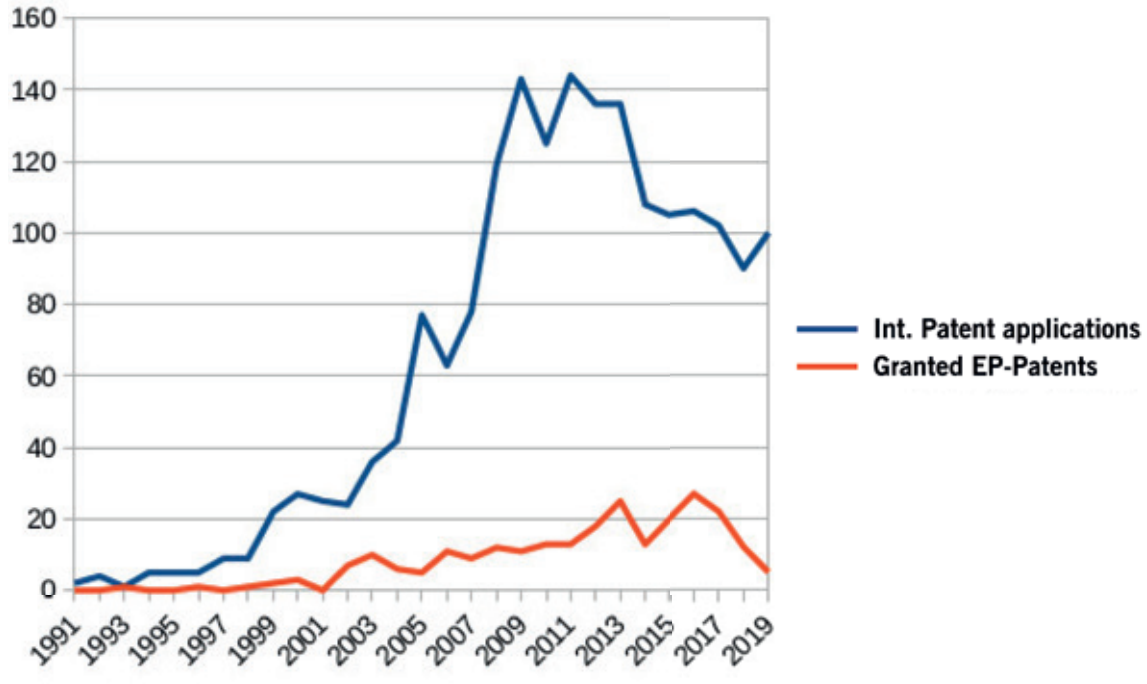


Figure 2: Number of patent applications (Applications) and patents granted on conventional plant breeding (Granted EP-Patents) by the EPO per year (own research). Soon, the number of granted patents might increase rapidly (see below).

Table 2: Overview on some plant varieties derived from conventional breeding, affected by European patents (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	128
EP2515630	Genetic markers associated with drought tolerance in maize	Syngenta	109
EP1804571	Resistance to virus in Capsicum plants	Monsanto	44
EP2451269	Plant resistant to a pathogen	Syngenta	40
EP0921720	Aphid resistance in composites	Rijk Zwaan	38
EP1525317	Clubroot Resistant Brassica Oleracea Plants	Syngenta	27
EP2242850	Maize plants characterized by quantitative trait loci (QTL)	Syngenta	24
EP1973397	Novel cucurbita plants	Syngenta	22

6. Overview: patent applications for conventional plant and animal breeding in 2018 and 2019

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 be valid. The WIPO itself does not grant any patents, but for many companies it is just 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 databases databases of the EPO with specific International Classifications (IPC A01H or C12N001582), names of relevant companies as well as on the analysis of the content of several hundred patent applications.

From the beginning of 2018 until the end of 2019, around 450 patent applications were filed for plants and plant breeding, with more than 100 patents covering conventional breeding; some of these overlap with patents on genetic engineering, especially with the new methods of 'genome editing'.

Our research found that around 70 patents on plants and plant breeding were the most relevant for this report. These were therefore examined in more detail. Others were put aside, especially if the technical description did not allow proper categorising.

Some examples revealed by the *No Patents on Seeds!* research were alarming, e.g. those applications covering:

- all the plants of one species derived from mutagenesis, regardless of the biological traits the plants might show;
- around 80 plant species all at once, with the described biological characteristics;
- all plants with desired biological characteristics, regardless of whether they are derived from random mutagenesis, genome editing or transgenesis or simply from crossing and selection;
- plants and seeds as well as the harvest and food products derived thereof;
- plants derived from phenotypical breeding with random mutagenesis as a 'technical topping' introduced just to make them patentable;
- specific DNA sequences and all cells and plants that inherit them.

Most patent applications were filed by Bayer (Monsanto) followed by the company Rijk Zwaan. No Patents on Seeds! approached the Dutch company and invited to comment. In April 2020, Rijk Zwaan, while not agreeing with all details of the report, it showed some agreement by stating: "Over the past decades, we have been confronted with patents entering the plant breeding arena. Although patents on technical inventions can contribute to innovative strength, extending patents to cover biological material can hinder innovation. This we consider an undesirable consequence of patents when used in plant breeding. In this respect, we do not differ much with *No Patents on Seeds!* in their conclusion that granting patents on traits in se should not be preferred." There might indeed be cause for concern since, as shown in Figure 4, the numbers of all plant patent applications per year is much higher for the agrochemical companies (such as Bayer) compared to traditional breeders such as Rijk Zwaan.

Thus, in the long-term, it is unlikely that traditional breeding companies can survive as independent entities under these conditions. As experience shows, the dynamics within the patent regimes mostly benefit the larger companies.

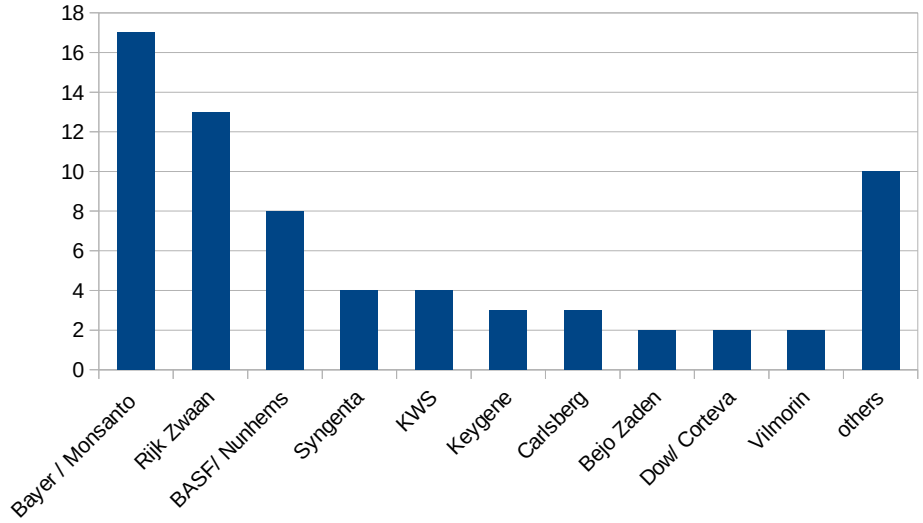


Figure 3: Companies which filed patent applications at WIPO 2018 – 2019 on conventional breeding (own research).

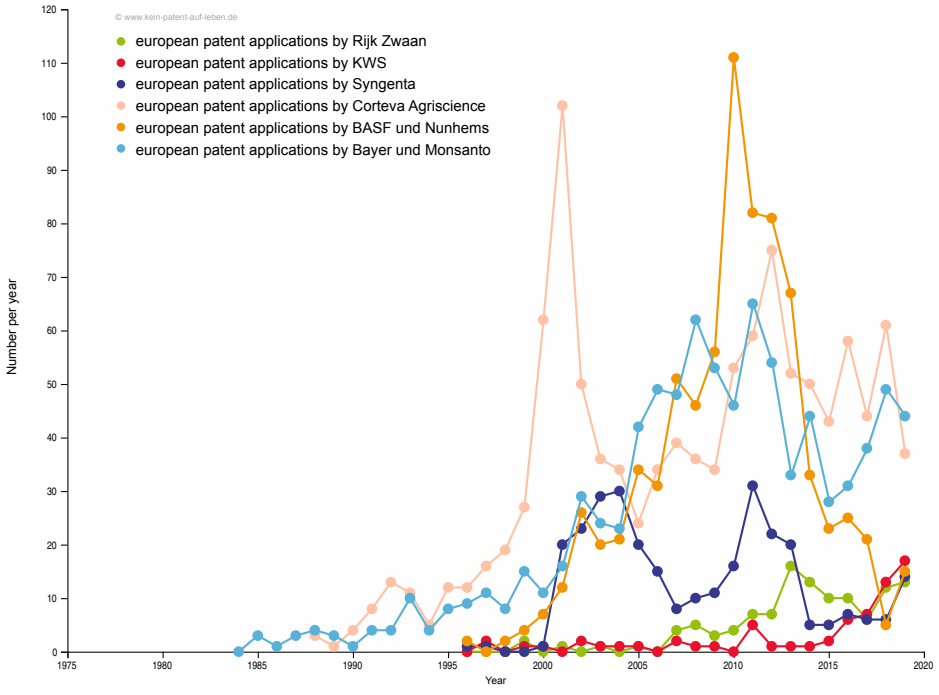


Figure 4: Patents on plants - number of patent applications for all plants under PCT/WIPO categorised by companies. Research according to official classifications (IPC A01H or C12N001582).
Source: www.kein-patent-auf-leben.de/patentdatenbank

Most patents were for breeding melons, followed by spinach, maize and tomatoes. Plant species explicitly mentioned in several of the patents are listed in Figure 5; other patents cover alliums, artichokes, eggplants, bananas, basil, beet, broccoli, cassava, cauliflower, celery, cotton, endive, potatoes and rice.

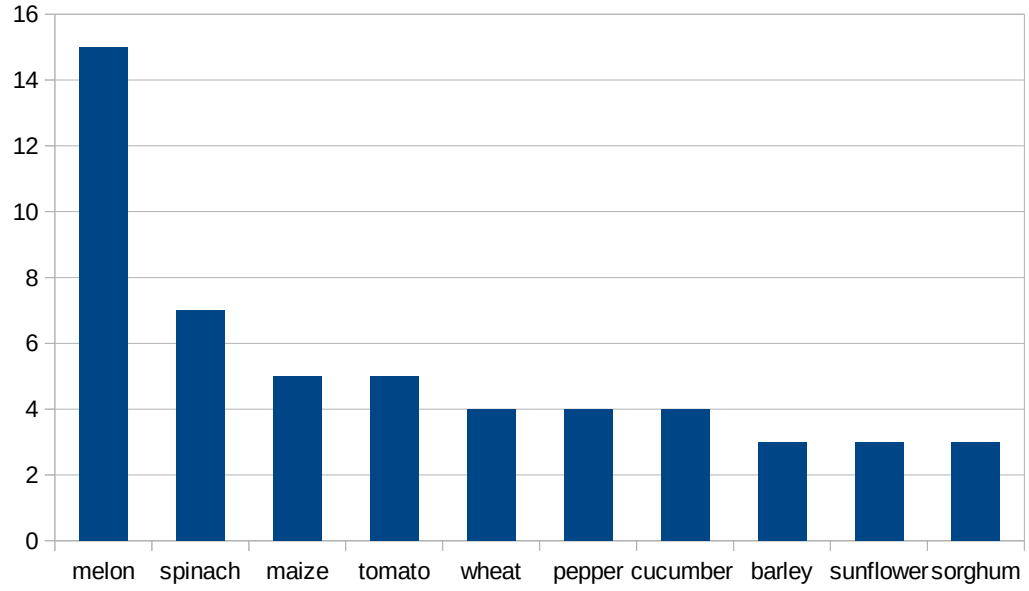


Figure 5: Plant species most frequently named in patent applications claiming conventional breeding filed at WIPO 2018 – 2019 (own research).

In addition, we carried out a more detailed examination of ten patent applications claiming livestock. These examples covered species such as cattle, pigs, sheep, horses, goats, rabbits and poultry. The patents claimed breeding methods and characteristics such as increased muscle tissue, sex selection and acceleration of the breeding process (for more details see below).

7. Exploiting legal loopholes: four patent applications based on random mutations in plants

In June 2017, the Administrative Council based its decision on a proposal made by the previous President of the EPO that allowed patents on genetic variations ('mutations').[26] No differentiation is made between naturally occurring gene variants and random mutations or technical interventions brought about by genetic engineering, including use of new methods such as genome editing (e.g. 'gene-scissor' CRISPR/ Cas applications): *"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."*[27]

This interpretation of random processes considered to be patentable technical inventions is blurring the fundamental difference between targeted technical interventions (genetic engineering) and conventional breeding.

The wording introduced by the previous President of the EPO, even allows for patents on mutations occurring spontaneously in nature: *"Some forms of mutagenesis occur in nature (usually called spontaneous mutagenesis). However, whether a specific mutation indeed would occur as the result of spontaneous mutagenesis is entirely speculative. (…) The mere possibility that a claimed mutated plant might also result from a natural (i.e. non-technical) process thus does not permit to extend the envisaged exclusion to mutant plants which the patent application describes as being obtained and produced through the application of mutagenesis techniques resulting in the modification of the genome and the achievement of a technical effect."*[28]

In short, this paragraph says: all kind of mutations and genetic variations, no matter whether they occur naturally or are randomly induced, are simply considered to be technical inventions as is the case with genetic engineering.

This decision of the Administrative Council, for the first time, explicitly opened up legal loopholes for patents on all kinds of random mutations by defining them as technical inventions. Since then, more and more companies have started to refer to random mutations in their patent applications to make their plants 'inventive'. In our research, we found around 30 examples of applications filed at the WIPO for random mutations in 2018 and 2019. These often serves as a 'technical topping' to create patentability according to the new wording, even where the method was not actually applied. There are other examples where methods of genetic engineering are also mentioned in order to give the impression that the patent applications are based on technical processes.

The most commonly cited method in applications for patents on random mutations in plants is the use of chemicals such as EMS (ethylmethansulfonat). These chemicals are, for example, brought into contact with kernels. Afterwards, the plants with the desired characteristics are selected and used for further breeding. It has been known for around 50 years that EMS can induce mutations in plants. According to international data bases, there are more than 3000 varieties on the market that are known to originate from mutagenesis breeding. If random mutagenesis had been regarded as a patentable technical invention in the past, a large number of plant varieties already on the market would have been subject to monopoly claims.

In the following section we show four examples of filed patent applications claiming random mutagenesis.

26 https://www.epo.org/modules/epoweb/acdocument/epoweb2/256/en/CA-56-17_en.pdf
27 www.epo.org/modules/epoweb/acdocument/epoweb2/256/en/CA-56-17_en.pdf, paragraph 40
28 www.epo.org/modules/epoweb/acdocument/epoweb2/256/en/CA-56-17_en.pdf, paragraph 41



7.1 All cassava (manioc) plants, regardless of specific breeding objectives

Patent application WO2019121603 covers all cassava and manioc plants (*Manihot esculanta*) which undergo chemical mutagenesis, regardless of which biological characteristics are ultimately achieved. What does the company claim to have 'invented'? The Dutch company Keygene claims to be the first to perform mutation breeding with chemicals on cassava. Chemicals are brought into contact with the plant cells. However, instead of just claiming the process of applying the chemical, the company claims all treated cells, seedlings and plants as their patented invention. Cassava (manioc) is an extremely important food in many countries, especially in Africa, South America and Asia. Therefore, if such a broad-based patent is granted, it could cause huge restrictions on breeding activity, e.g. in developing varieties adapted to new climatic conditions or able to cope with new pests. These restrictions might also affect African countries, even if the patent is only granted in Europe, since many breeding processes involve international cooperation. Such broad-based patent claims can be seen as an intended abuse of the patent system to gain control over breeders and to misappropriate breeding resources.

This example shows how important food plants are being turned into the 'intellectual property' of companies merely by applying simple, non-technical methods. The companies try to exploit the legal loopholes introduced by the Administrative Council in their 2017 decision, which explicitly declared random mutations to be patentable 'inventions'.



7.2 A patent covering 80 plant species

The company Kleinwanzlebener Saatzucht (KWS), together with the University of Zuerich, claims around 80 plant species resistant to the fungal disease northern corn leaf blight (WO2019038339, EP3447135) that occurs, e.g. in maize. What does the company claim to have 'invented'? KWS exposed plants from several sources to the fungal disease. The plants which showed resistance were analysed in more detail, and the relevant DNA sequences related to the biology of the cell membrane and its response to the disease were identified.

Random mutagenesis was subsequently carried out using well-known procedures (applying chemicals to pollen), and plants inheriting the desired DNA sequence were identified.

Furthermore, the patent is not restricted to random mutagenesis but extended to every conceivable method that might be used, including new methods of genetic engineering.

Equally, patent claim 13 encompasses *"preferably a stable introduction mediated by conventional plant breeding, or a stable introduction by means of molecular biology, comprising genome editing, or a combination thereof."* (claim 13).

Based on this concept, the company claims not only the application of the method, but also all the resulting plants and offspring thereof from around 80 plant species. Species such as barley, sorghum, corn, rice, beets, rape, eucalyptus and onions are listed.

Claim 9 includes *"Hordeum vulgare, Hordeum bulbusom, Sorghum bicolor, Saccharum officinarium, Zea spp., including Zea mays, Setaria italica, Oryza minuta, Oryza saliva, Oryza australiensis, Oryza alta, Triticum aestivum, Triticum durum, Secale cereale, Triticale, Malus domestica, Brachypodium distachyon, Hordeum marinum, Aegilops tauschii, Daucus glochidiatus, Beta spp., including Beta vulgaris, Daucus pusillus, Daucus muricatus, Daucus carota, Eucalyptus grandis, Nicotiana sylvestris, Nicotiana tomentosiformis, Nicotiana tabacum, Nicotiana benthamiana,*

Solanum lycopersicum, Solanum tuberosum, Coffea canephora, Vitis vinifera, Erythrante guttata, Genlisea aurea, Cucumis sativus, Marus notabilis, Arabidopsis arenosa, Arabidopsis lyrata, Arabidopsis thaliana, Crucihimalaya himalaica, Crucihimalaya wallichii, Cardamine nexuosa, Lepidium virginicum, Capsella bursa pastoris, Olmarabidopsis pumila, Arabis hirsute, Brassica napus, Brassica oleracea, Brassica rapa, Raphanus sativus, Brassica juncacea, Brassica nigra, Eruca vesicaria subsp. sativa, Citrus sinensis, Jatropha curcas, Populus trichocarpa, Medicago truncatula, Cicer yamashitae, Cicer bijugum, Cicer arietinum, Cicer reticulatum, Cicer judaicum, Cajanus cajanifolius, Cajanus scarabaeoides, Phaseolus vulgaris, Glycine max, Gossypium sp., Astragalus sinicus, Lotus japonicas, Torenia fournieri, Allium cepa, Allium fistulosum, Allium sativum, Helianthus annuus, Helianthus tuberosus and Allium tuberosum (…).

This example shows how the company has used a 'technical topping' to hide the fact that there is no proper invention. In reality, they used standard conventional breeding methods, such as exposure to plant diseases, followed by further crossing and selection. KWS claims an extremely broad range of plants as its invention, wholly based on a known method.

This example illustrates the systematic way in which the company exploited the legal loopholes in the 2017 Administrative Council decision, which left random mutations open to patentability as inventions. Moreover, the Administrative Council cleared the way for claims which systematically blur the fundamental differences between conventional breeding and genetic engineering.

Despite KWS is concerned about patents in conventional breeding might trigger problems for plant breeding innovation[29], the above patent application still tries to exploit the the legal loopholes in the 2017 Administrative Council decision, which left random mutations open to patentability as inventions. By doing so, the company is blurring the fundamental differences between conventional breeding and genetic engineering.

7.3 Endive plants derived from a 'hot water test'



The Dutch breeder Rijk Zwaan claims endive plants (*Cichorium endivia L.*) which are non-browning after being brought in contact with warm water (EP3427575). What does the company claim to have 'invented'? By bringing leaves from endive plants into contact with hot water, plants showing a non-browning phenotype were identified. These plants can be used for further breeding to achieve the desired characteristics.

In addition, after performing random mutagenesis (by using EMS chemicals), other plants with the relevant genotype were identified. However, this additional step is not necessary since suitable plants can easily be identified by using the 'hot water test'.

Again, mutagenesis was used as 'technical topping' to give the impression of a real invention. To add further confusion, methods such as "CRISPR … radiation, gene silencing, RNAi, or a combination thereof" are mentioned in the claims (claim 15), although these techniques were not used to produce the plants.

Furthermore, there is also a current example of a recently granted patent: in June 2018, one year after the decision of the Administrative Council, the EPO granted a patent on lettuce derived from conventional breeding (EP2966992). The patent claims the lettuce seeds, plants and harvest that can be cultivated in a hotter climate. The reason for granting the patent: DNA sequences were added to the application as a 'technical topping' to make the plants patentable according to current EPO rules – similar to the new patent application for endives. *No Patents on Seeds!* has filed an opposition against this patent.[30]

29 www.kws.com/corp/en/press-dialogue/press/kws-believes-the-epo%E2%80%99s-patent-decision-weakens-the-breeder%E2%80%99s-exemption/

30 https://www.no-patents-on-seeds.org/en/node/589

This case shows that the 2017 Administrative Council decision did, in fact, leave the door wide open to the evasion of prohibitions in regard to patents on conventional breeding by allowing the patentability of random mutations as inventions. The Administrative Council also opened the door to overlapping claims, covering both genetic engineering (genome editing) and conventional breeding.

7.4 Further patents on beer



The company Carlsberg, one of the largest breweries in the world, was heavily criticised in public for three 'patents on beer' that were granted in 2016 and 2017 (EP2384110, EP2373154 and EP2575433). Oppositions were filed against these patents, involving around 40 organisations.[31] While no final decisions have been taken on these patents, the company has once again used well known processes of random mutagenesis to turn seeds, plants and resulting food and beverages into an 'invention'. Our research discovered three further patent applications filed in 2019 (WO2019129736, WO2019129739, WO2019134962). What is the 'invention'? Seeds from barley plants were brought into contact with chemicals (EMS) after which further selection was carried out for desired characteristics, such as changes in starch composition. Even though there is nothing new or technical in this process, the company is claiming the resulting seeds, plants, harvest, food and beverages as its invention.

This example again shows how the legal loopholes in the June 2017 Administrative Council decision can be exploited because random mutations are now considered to be patentable inventions. It opens up the way for big corporations to gain monopoly rights over our daily food from field to fork, from barley to beer, without ever having invented anything.

8. Exploiting the legal chaos: four patent applications on diverse methods of conventional plant breeding

In June 2017, the Administrative Council of the EPO decided that patents on plants and animals derived from processes of conventional breeding would no longer be granted. More specifically, the decision excluded patents on those plants and animals bred by crossing and selection. As a consequence, the EPO revoked the Monsanto patent on 'severed broccoli' (EP 1597965). This broccoli variety, which is derived from crossing and selection, is supposed to grow a little bit higher and can therefore be harvested more easily.[32] However, after a decision taken by the Technical Board of Appeal of the EPO (T1063/18) nullified the decision of the Administrative Council, Monsanto (Bayer) has now announced it will file an appeal against this decision (T2840/18).

No Patents on Seeds! has found many new patent applications filed in 2018 and 2019 that exploit this legal chaos in a similar way to Monsanto`s attempt in the case of the broccoli. They are once more trying to claim plants derived from all methods used in conventional breeding, including crossing and selection, as their invention.

In the following sections, we have included four examples from our research which are also representative for around 50 recent of patent applications, all claiming many different methods of conventional breeding and the resulting plants.

31 www.no-patents-on-seeds.org/sites/default/files/2018-10/PR%20hearing%20patent%20on%20beer_0.pdf
32 https://www.no-patents-on-seeds.org/en/patent-cases/severed-broccoli



8.1 Muskmelons with red flesh

Together with its vegetable breeding company, Seminis, Monsanto (Bayer) filed a patent claiming muskmelons (*Cucumis melo*) with red flesh (WO2019040455). What does the company claim to have 'invented'? The melons were simply characterised according to their colour. Subsequently, plants producing melons with intensive red flesh were crossed with other melons to combine the colour with sweet taste and early ripening.

Afterwards, some marker genes were identified that could be used to select the desired plants. In the patent, the company claims the plants as well as seeds inheriting a trait that makes the flesh of the melons red. The harvested melons are part of the 'invention'.

The patent shows how normal plant breeding, based on the selection of a phenotype, is turned into an invention with zero technological effort, simply by adding some 'technical toppings' such as marker genes. These kinds of patents were excluded from patentability in the 2017 Administrative Council decision. However, the patent might nevertheless be granted if the legal uncertainty arising from the decision taken by the Technical Board of Appeal of the EPO in 2018 (T1063/18) prevails.



8.2 Cereal plantlets stored in a refrigerator

Bayer filed a patent application for cereal plants derived from plantlets stored in a liquid at a low temperature for several weeks (WO2019001793). Surprisingly, these plants showed a higher yield after planting. What does the company claim to have invented? As Bayer states in its patent, this was a chance observation (page 2): "*This invention is based on the serendipitous observation that cereal plantlets, such as wheat plantlets … temporarily immersed in a liquid medium at low temperature had a higher yield.*"

While this observation might be surprising, it is based on what is called an epigenetic effect: stress conditions during storage causing a change in gene regulation of the plant cells, which then resulted in increased yield under normal growing conditions. For example, reaction to cold is known to be an important factor in enhancing germination in many plant species. In other words, this was simply a 'normal' biological response, not a technical intervention or an invention.

This example highlights a further attempt to exploit the loopholes in the 2017 Administrative Council decision, according to which only crossing and selection as "*essentially biological*" breeding methods are excluded from patentability. The Administrative Council did not take into account that there are other techniques used in conventional breeding which are "*essentially biological*" but not technical.



8.3 US biopiracy: claiming Mexican pepper plants

The University of California applied for a patent on pepper plants (*Capiscum annuum*) with a "low destemming force" which means the peppers can be harvested more easily (WO2019191675). The plants were originally collected in Mexico and subsequently crossed with varieties marketed in New Mexico (USA): "*We have screened a set of wild and semi-domesticated pepper accessions recently collected in regions of Mexico for disease resistance and horticultural traits. Among these is a semi-domesticated C. annuum accession, UCD-14, that has oblong fruit with firm texture and medium pericarp thickness that easily abscises when picked at the mature green stage, leaving the pedicel and calyx behind (destemmed). This line has been crossed with jalapeno, New Mexican ('NuMex Garnet') and blocky ('Maori) types. We have shown that the destemming trait can be readily transferred through a phenotypic evaluation (…)*".

In addition to these non-technical steps in breeding, which are at the heart of the alleged 'invention', the University of California added further "technical toppings" that are not necessary to breed the plants. DNA sequences were identified that correlate with the selected phenotype and which are supposed to enable the identification of relevant plants by genotyping. The patent claims the method of selecting and crossing and also the resulting plants and a method to harvest the peppers by "*shaking the pepper plant*".

This patent shows how normal plant breeding based on the selection of a phenotype is turned into an invention with zero technological effort, simply by adding some information on marker genes. These kinds of patents were excluded in the 2017 Administrative Council decision. However, the patent might nevertheless be granted as long as the legal uncertainty resulting from the 2018 decision taken by the Technical Board of Appeal of the EPO prevails.



8.4 Downy mildew-resistant basil - found in natural populations

BASF, together with its subsidiaries Hild (Germany) and Nunhems (Netherlands), claims downy mildew-resistant (a fungal plant disease) basil plants (*Ocimum basilicum*) (WO2019068647). What does the company claim to have 'invented'? Wild plants 'found' in a USDA seed bank (India and other regions in Asia are believed to be the origin) were found to show resistance to downy mildew and were subsequently crossed with commercially traded varieties.

In summary, the process described in the patent starts with well-known methods of exposing plants to diseases. Plants identified during this process can be used for further breeding without any further technicalities. In addition, the company performed some technical procedures, which are, however, not necessary to obtain the respective plants, but are simply used as a 'technical topping' to hide the fact that there is no real invention: some DNA sequences were identified that correlated with the desired phenotype (marker genes), and which were supposed to enable identification of the plants via genotyping. In the patent, BASF claims the plants as well as pollen and seeds and all further breeding with the patented basil as its 'technical invention'.

These kinds of patents were excluded in the 2017 Administrative Council decision. However, the patent might nevertheless be granted if the legal uncertainty resulting from the decision taken by the Technical Board of Appeal of the EPO in 2018 (T1063/18) prevails.

9. Three patent applications for gaining monopolies in livestock breeding



The European Patent Office has already granted several patents on the conventional breeding of animals. In particular, in 2007/2008 several patents were granted for the breeding of pigs and cattle. Patents on animals can have a huge impact on agriculture: for example, if patents on cattle are granted, farmers can still sell the milk and meat but cannot use the animals for further breeding without the consent of the patent holder. Most of these patents were revoked after opposition by civil society organisations.[33]

However, in 2018 a patent was granted on salmon fed with specific plants (EP1965658). The patent claims the salmon and the fish oil. *No Patents on Seeds!* filed an opposition in 2019.[34]

More than 10 new patent applications covering the conventional breeding of livestock were filed in 2018 and 2019. These patents can all be granted unless the uncertainty and legal chaos around patents on conventional breeding is stopped.

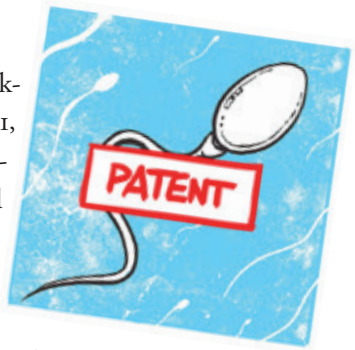
9.1 Selecting genes and claiming a whole herd

The Livestock Improvement Corporation Limited (New Zealand) has laid claim to a patent on breeding dairy cows based on analyses of a specific gene (WO2019125187). What does the company claim to have 'invented'? The company compared breeding traits such as milk production in dairy cows with data from genetic screening using standards methods. They identified the variant of a naturally occurring gene that is supposed to influence the amount of milk a dairy cow produces.

The company claims the "*generation of animals"* and *"forming a herd"* simply by using a test to identify the relevant gene. The way the claims are phrased means that not only the method but also the resulting dairy cows would fall within the scope of the claims.

This example shows another attempt to exploit the loopholes in the 2017 Administrative Council decision which considered usage of random mutations and gene variants for breeding as patentable inventions.

9.2 Selecting cells and 'inventing' sperm



The French company Genes Diffusion uses a technical device and a fluorescent marker to select sperm cells according to the expected sex of the offspring (WO201834281, EP3570978). What does the company claim to have 'invented'? They describe a technical process of separating cells according to their sex. The technical device can be used for cattle, pigs, sheep, horses, goats and rabbits. The company claims the technical process and the selected sperm cells as its 'invention'.

If the patent is granted, the breeding material will be controlled by the patent owner. Patents on sperm cells used in animal breeding are already a major issue in the US, where Inguran has a far-reaching patent monopoly on sex selection in cattle breeding; other companies challenging Inguran in this very competitive sector include Genus and ABS global.

33 www.no-patents-on-seeds.org/sites/default/files/2019-09/Background%20Patents%20on%20animals%20for%20food%20production%20(2019).pdf

34 www.no-patents-on-seeds.org/sites/default/files/2019-07/PR%20Opposition%20against%20patent%20on%20salmon%20and%20trout.pdf

This patent shows that appropriation of biological material necessary for animal breeding might also become an issue in Europe. Therefore, the Administrative Council tried in June 2017 to exclude patents on animal germ cells that can be used for propagation (gametes). However, the patent might nevertheless be granted if the legal uncertainty resulting from the decision taken by the Technical Board of Appeal of the EPO in 2018 prevails. Patents on gametes of animals, such as sperm cells or oocytes, might ultimately allow the patent holder to control, intervene, hamper or even block conventional livestock breeding.



9.3 Embryos to 'replace' breeding animals

Inguran is a US company with a history of filing patents on livestock breeding and engaging in long lasting legal battles in the US over patents, often involving other companies such as Genus and ABS Global. Inguran is now trying to expand its business and obtain a patent on using embryos of mammalian species for the extraction of cells (gametes, such as oocytes and sperm cells) to be used in further breeding (WO2019100018). This would mean that several breeding generations can be created without involving adult animals: *"the invention encompasses selecting one or more embryos - rather than reproductively mature animals - as parents of the next generation in a breeding programme"*.

What does the company claim to have 'invented'? In short, Inguran proposes extracting gametes from embryos: *"One aspect of the invention comprises deriving gametes, both oocytes and sperm, directly from in vitro, or in vivo, embryos."* They list mammalian species such as *"swine, ovine, bovine, equine, deer, elk, buffalo, or the like (…)."* Also *"non-human mammalian species such as canines and felines, as well as primates, including but not limited to chimpanzees, and gorillas, as well as whales, dolphins and other marine mammals"* are listed in the description of the patent.

The 'invention' is supposed to save on costs and speed up breeding: *"the invention allows a breeder to greatly reduce or entirely eliminate the need for maintaining and caring for young and adult animals"*. Inguran suggests applying the process over several generations: *"This process is repeated multiple times, with each set of derived gametes used to generate a subsequent generation of embryos."* The patent application includes an additional technical topping, i.e. generating embryos via methods such as cloning and using embryonic stem cells.

Inguran's patent even claims the method to *"generate a line of non-human mammalian species."* The wording of the claim means that any resulting animals are considered to be a patented invention.

The 'invention' raises substantial and profound ethical questions related to animal welfare, which have apparently been set aside in favour of expected profits. The embryos are obtained from brood animals that are subsequently destroyed – this is clearly animal cruelty and would unnecessarily turn breeding into an abuse of animal welfare.

This example shows how companies are trying to introduce technical aspects into conventional breeding which allows them IP rights. Even though ultimately the patent is based on crossing and selection (of embryos) it might escape the prohibition as defined in the decision taken by the Administrative Council in 2017, which allows patents even in cases where no targeted technical intervention is involved. The patent application clearly shows the need to restrict patents in animal breeding to purely technical processes which do not involve any animal suffering.

10. Conclusions and demands

The basis for European patent law, the so-called European Patent Convention (EPC), in essence excludes conventionally bred plants and animals from patentability. As Article 53 (b) (↗ Glossary) states, no patents on plant or animal varieties may be granted:

> *"European patents shall not be granted in respect of: […] plant or animal varieties or essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof."*

However, in recent years the European Patent Office EPO has granted thousands of patents on plants and animals, mostly eroding the prohibitions in the EPC.

Our research has now found dozens of new patent applications on conventional plant and animal breeding. From the beginning of 2018 until the end of 2019, around 450 patent applications were filed for plants and plant breeding, with more than 100 patents covering conventional breeding.

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:

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 necessary changes can possibly be brought about by clarifications in the Implementing Regulations of the EPC. However, if the Administrative Council is not able to solve the problem, a Conference of the Contracting States has to change the text of the EPC in order to introduce legal certainty and clarity for breeders, gardeners, farmers and consumers in Europe. It has to be made clear that all processes used in the conventional breeding of plants and animals and all products derived thereof cannot be patented.

Glossary

- **Administrative Council:** The Administrative Council[35] represents the 38 contracting states of the European Patent Convention (EPC), comprising all the member states of the European Union together with Albania, the North Macedonia, Iceland, Liechtenstein, Monaco, Norway, San Marino, Serbia, Switzerland and Turkey as well as the UK. 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)[36] 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[37] 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[38] is the highest legal decision-making body of 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[39] 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[40] 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[41] 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 28), but then called into question by the EPO (decision T1063/18). The new rule 28 (2)[42] 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."*

35 https://www.epo.org/about-us/governance/administrative-council_de.html
36 https://www.epo.org/law-practice/legal-texts/html/epc/2016/e/ar53.html
37 https://www.epo.org/law-practice/legal-texts/html/epc/2016/d/ar172.html
38 https://www.epo.org/law-practice/case-law-appeals/eba_de.html
39 https://www.epo.org/law-practice/legal-texts/html/epc/2016/d/ma1.html
40 https://www.epo.org/index_de.html
41 https://www.epo.org/law-practice/legal-texts/html/epc/2016/d/ma2.html
42 https://www.epo.org/law-practice/legal-texts/html/epc/2016/d/r28.html

- **Plant Variety Protection System (PVP):** The System of Plant Variety Protection of UPOV (International Union for the Protection of New Varieties of Plants)[43] is an intellectual property right that gives breeders an exclusive right to the production and sale of new varieties over a period of 25 to 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[44] is responsible for cases that are not decided in the first instance.
- **Unitary Patent and Unified Patent Court:** In future, the EPO will grant patents with a "unitary effect" under the new so-called "Unitary Patent"[45] regime. This will not change the way patents are examined, but will make it easier for patents to come into effect 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 obtain patent protection will be lowered, the fees to challenge the patents in the Unified Patent Court are very high.

43 https://www.upov.int/portal/index.html.de
44 https://www.epo.org/law-practice/case-law-appeals/about-the-boards-of-appeal/technical-boards-of-appeal_de.html
45 https://www.epo.org/law-practice/unitary/unitary-patent_de.html