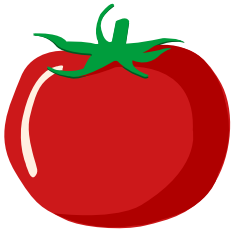
NO PATENTS ON SEEDS!

Patents on genes and genetic variations can block  access to biological diversity for plant breeding

Patent research conducted in 2021 shows how industry is trying to patent genes, plants, seeds and food

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Patents on genes and genetic variations block access to biological diversity for plant breeding

Patent research conducted in 2021 shows how industry is trying to patent genes, plants, seeds and food

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Executive Summary

The problem:

Patents that are granted on usages of naturally occurring genes, on seeds, on plants and their harvest, represent one of the biggest threats to global food security and regional food sovereignty. Patents create monopolies: if patents are granted on conventionally-bred plants and animals within its geographic scope, the patent holder can exclude other breeders from using them to bring new varieties to the market - or make breeders dependent on license contracts. In many cases, the patents also cover the use of the harvested plants in food production and food products.

As a recent patent granted by the European Patent Office (EPO) shows (EP 3560330), plants derived from randomly mutated genes and the usage of naturally occurring genetic variations within the process of conventional breeding, are indeed regarded as patentable 'inventions'.

Patents on usages of naturally occurring genes and randomly mutated plants can hamper or even block the use of biological diversity for future breeding, independently of whether plants or animals are being targeted. Such patents can lead to small and medium-sized breeders being confronted with 'patent thickets'. Breeders are currently protected by the breeder's exemption, which is part of the European plant variety protection system; it guarantees free access and freedom to operate in Europe - this could, however, soon become a thing of the past.

If these developments are not stopped, it will mean the end of plant breeding as we know it: traditional breeders can no longer use existing varieties or screen native populations to bring new varieties to the market without risking patent infringement. Consequently, many breeders may stop breeding or become dependent on large companies by signing license contracts with patent holders.

The consequences would not be confined to breeding: in many cases, the patents also cover the use of the harvested plants for food production and the food itself. As a result, a handful of large international corporations will acquire far-reaching control over the production of our food. They will decide what we eat, what farmers produce, what retailers sell and how much we all have to pay for it. This development will also have harmful consequences for the Global South.

Patents on genes and the use of biological resources needed for conventional breeding are an abuse of patent law. Commonly available genetic variations originating from wild populations or bred varieties will become the private property of companies. In some cases, this could qualify as biopiracy, especially if the corporations have violated international treaties to gain access to resources and/or ignored fair benefit-sharing (for a detailed discussion of this topic see Annex 3).

The ongoing European Patent Office 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 some legal loopholes: the EPO failed to consider the fundamental differences between genetic engineering (patentable) and conventional breeding (not technical, non-patentable). In current EPO practice, plants derived from random genetic changes are considered to be patentable inventions.

Several companies are well aware of the legal loopholes and are, therefore, filing increasing numbers of patents on usages of naturally occurring genes as well as on randomly generated genetic variations. The EPO grants patents on plants which inherit randomly mutated genes. Also the usage of naturally occurring genetic variations for selecting plants and animals within the process of conventional breeding is subjected to patent claims. This report provides an overview of recent patent applications as well as the most recent decisions taken by the EPO.

The strategy of the large companies:
As shown in the overview of patent applications provided in this report, companies such as BASF, Bayer-Monsanto, Syngenta or KWS, all appear to systematically engage in the greatest possible exploitation of legal loopholes. They screen the genomes of plants to find random mutations and variants of interest to then claim them as their inventions. Some of the patent applications published in 2021 cover dozens, hundreds or even thousands of genetic variations identified in cereals such as soybeans and maize; or in vegetable species such as potatoes, spinach, lettuce, cucumber; or fruit plants such as tomatoes and melons. The companies then claim patent protection for all further usages of these particular genes and variants of genes, regardless of the method of breeding.

At the same time, the companies also use specific wording in the patent applications they file, i.e. they blend technical elements (genetic engineering) with standard methods of conventional breeding to give the impression of a technical invention.

If such patents are granted, there will be huge implications for breeders, farmers and consumers, who will all become more and more dependent on large companies able to control access to biological resources needed for further breeding. As a recent patent granted by the EPO shows, monopoly rights are indeed issued on the usage of naturally occurring genetic variations for screening and selecting plants (animals) within the process of conventional breeding. Randomly mutated genes and plants inheriting these gene variations are also patented. Political decisions need to be taken as soon as possible – otherwise ongoing legal uncertainty will undermine traditional plant and animal breeding, thus threatening global food security.

The political demands:
No Patents on Seeds! wants to safeguard 'freedom to operate' for all European breeders, gardeners or farmers who are engaged in conventional breeding, who grow conventionally-bred plants or farm animals. Access to biological diversity needed for conventional breeding must not be controlled, hampered or blocked by patents. Global food security and food sovereignty must not be endangered by exclusive property rights to biological diversity needed in plant breeding.

Extended Summary

The back door left wide open to patents on conventionally-bred plants and animals

In June 2017, the Administrative Council (↗ „Glossary") of the European Patent Office (EPO) decided that patents on conventionally-bred plants and animals would 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 victory for the interests of the general public, and 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. One specific reason for concern in this respect is that the Administrative Council based its decision on a document prepared by the previous President of the EPO (CA/56/17). The wording of this document does not differentiate between spontaneously occurring gene variants and random mutations, on the one hand, and technical interventions generated via genetic engineering (including genome editing), on the other hand. Therefore, in current EPO practice, randomly generated mutations and plants (and animals) inheriting such genetic variations, are considered to be patentable inventions.

This practice has opened the door to an increasing number of patents: in 2016, the EPO, for example, granted patents on barley for brewing that was developed using random mutagenesis. Since then, companies have filed more and more patents on randomly generated genetic variations as well as on usages of naturally occurring genes, regardless of whether they originate from native populations, from existing varieties or from random mutagenesis.

Recent examples of patent applications on biological diversity potentially blocking plant breeding:

(1) Patent applications filed by Syngenta /ChemChina claim the use of thousands of naturally occurring genetic variations (also known as single nucleotide polymorphism, SNPs) found in food plants, such as soybeans and maize, which can, for example, enhance resistance to plant pests (WO2021000878, WO202103391, WO2021154632, WO2021198186, WO2021260673). In most cases, the relevant genetic variations were identified in wild relatives of the domesticated varieties and introduced by crossing and selection.

The company claims the usage of the described genetic variants for all breeding purposes and all plants inheriting the genetic variations from any previous breeding. The patent refers to genetic engineering techniques (including applications of CRISPR/Cas) as well as traditional methods of plant breeding, such as screening for the gene variations of interest and further crossing and selection. The patent covers all the resulting plants, including seeds and harvest.

This means that other breeders will be discouraged by the immense legal uncertainty. For example, it would be practically impossible to find out whether the genome of a particular soybean plant with enhanced resistance to Asian soy rust has any of the circa 5000 SNPs listed in patent application WO2021154632. Breeders would, therefore, no longer be able to use existing plant varieties for further breeding. They could not even use of the populations of wild relative species of soybeans for breeding because the patent covers all usages of the relevant genes. In effect, these patents represent an impenetrable jungle for all other plant breeders.

(2) The cultivation of tomatoes resistant to a virus known as Tomato Brown Rugose Fruit Virus (ToBRFV, also called Jordanvirus) is another alarming instance. In this case, several companies are claiming various genomic regions identified on several chromosomes in the genome of the tomatoes. For example, 10 patents filed by five different companies (e.g. Bayer/ Seminis, BASF/Nunhems and Rijk Zwaan) are directed at chromosome 11, all claiming similar and partly overlapping genomic regions. All tomato plants inheriting these genetic variations generated through whatever kind of breeding are claimed as an invention. The genetic variations claimed in the patent occur naturally and are found, in particular, in wild species of tomatoes.

Conventional breeders aiming to produce tomato varieties with resistance to the virus will, in many cases, not know the exact genotype of their plants. Therefore, to avoid patent infringement, they would have to analyze around a dozen patent applications and screen for all genetic variants described in the patent. In addition, they may have to enter into about a dozen license contracts. With such impediments, many breeders will simply come to the conclusion that they cannot breed those particular tomatoes without incurring fees for expensive patent attorneys or comprehensive laboratory analyses.

The end result is 'over-patenting', which effectively blocks access to the biological material needed in traditional breeding to generate the desired virus resistance. Consequently, the legal uncertainty and the threat of expensive legal battles are likely to prevent breeders from generating urgently needed tomato varieties – this will be left to a few large companies.

Until now, under the plant variety protection regulations, all breeders could freely use all existing varieties to breed and market new and better plant varieties. Plant variety protection plays a huge part in innovative breeding – something that could now be blocked by a 'thicket' of patent applications with claims on the genome of food plants.

Recently granted patents show that conventional plant breeding will indeed be impacted by this development, including climate change adaptation:

(1) EP 2440664 was issued in April 2022 to BASF/Nunhems. The patent claims tomato plants with improved drought tolerance, including the fruit and seeds. The relevant genetic information was identified in wild relatives of tomatoes. Specific gene variations were selected, the respective plants were subsequently crossed and further selected to establish the trait in marketable varieties. The patent covers all plants with the desired characteristics, regardless of whether they are derived from conventional breeding or genetic engineering. Climate change poses huge challenges, including the question of how to adapt our food plants. Against this backdrop, access to biological diversity needed for future breeding must not be controlled, hampered or blocked by patents.

(2) (2) In April 2022, the EPO announced that it was granting patent EP2961263 to Bejo Zaden. The patent claims lettuce (Latuca sativa) which contains genes originating from a wild relative. The plants were bred using crossing and selection. According to an industry database (PINTO), this single patent targets more than 100 conventionally-bred varieties. The same database also shows that, in Europe, already more than 800 conventionally-bred varieties are patented, of those, around 120 are targeted by several patents in parallel.

(3) In June 2022, a patent (EP 3560330) was granted to the German company, KWS, claiming maize with improved digestibility, regardless of whether it was derived from randomly mutated genes or from genetic engineering. In addition, all usages of the genetic variations to screen and select for plants within the process of conventional breeding are the subject of monopolistic control. As it stands, this patent may considerably hamper or even block the production of conventionally-bred varieties with the desired trait. Such patents could severely impact the possibility of traditional breeders using the existing gene pools of plant species.

Legal background:

The EU Patent directive 98/44 EC is decisive in this context. This EU regulation was integrated in the Implementing Regulations of the European Patent Convention (EPC), which is binding for EPO decision-making.

As can be concluded from Recitals 1, 2, 52, 53 and Art.16, the EU directive addresses the technical developments in genetic engineering. There are historical reasons for this: before the directive came into force, the EPO had stopped granting patents on genetically engineered plants and animals (T356/93). However, this decision led to a sharp increase in pressure from companies claiming the genetically engineered organisms as their inventions. The EU directive can, therefore, be seen as a direct response to this pressure. At the same time, the directive gives no indication that the EU actually wanted to allow patents on conventionally-bred plants and animals.

There are two crucial legal provisions in the EU directive that are relevant in this context:
(1) On the one hand, the directive allows patents to be granted on technical inventions which concern plants and animals. For example, Art. 4 (2), allows patents to be granted *"if the technical feasibility of the invention is not confined to a particular plant or animal variety"*. This addresses the possibility of transferring isolated genes from one organism to another using genetic engineering techniques. At the same time, Art. 4 (1) of the EU directive and Article 53 (b) (↗ „Glossary") of the EPC prohibit patents on the conventional ("essentially biological") breeding of plants and animals.

Decisions taken by the Enlarged Board of Appeal (G2/07 and G1/08) make it clear that *"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",* while traits which are *"the result of the mixing of the genes of the plants chosen for sexual crossing"* are not a technical invention. However, despite decisions G2/07 and G1/08, the EPO still considers random mutations to be technical inventions.

(2) Art. 3 (2) of the EU directive allows patents on *"biological material which is isolated from its natural environment or produced by means of a technical process (…) even if it previously occurred in nature."* This article, e.g. allows patents to be granted on genes isolated from the human body (see Art. 5 of the directive). At the same time, a plant gene in a plant cell, a plant species or a family of plant species (which can be crossed with each other), cannot be considered to be 'isolated from its natural environment'. As shown by recent case, EPO grants patents on the usage of naturally occurring genetic variations within the process of conventional breeding. Consequently, access to the plants (and animals) naturally inheriting those genes is also hampered. These patents can thus severely impact the possibility of traditional breeders using the existing gene pools of plant species.

The EPO ignores that, in the context of plant and animals, there are specific provisions, such as Art. 4 of the EU directive and Art. 53(b), EPC), that make it necessary to restrict the scope of patents to technical inventions. While the examination guidelines of the EPO state that "thus transgenic plants and technically induced mutants are patentable, while the products of conventional breeding are not", the practice of the EPO shows the opposite is true. What is largely missing a meaningful distinction between technical processes (such the targeted insertion of a new trait) and essentially biological processes (such as usage of random mutations and genetic variations within conventional breeding).

Conclusions

Patents create monopolies: if patents on plants and animals are granted, all other breeders can be blocked from using them for producing new varieties - or could become dependent on license contracts. In many cases, the patents also cover the use of the harvested plants in food production.

As shown in the overview of patent applications and granted patents provided in this report, several companies are actively making every effort to exploit existing legal loopholes to claim conventionally-bred plants as their own invention. Both the companies and the EPO appear to be trying to systematically blur the distinction between conventional breeding and genetic engineering. All plants (or animals) bred in future with the characteristics described in the patents are claimed as an invention, regardless of whether they are derived from genetic engineering or randomly mutated genes. In addition, the usage of naturally occurring genetic variations for the selection of plants and animals needed within the process of conventional breeding is also subject to monopolistic control of the patent holder.

This strategy is a major cause of problems in regard to the scope of patents: Even though plants (or animals) derived from essentially biological methods of breeding are not deemed patentable, the patents granted by the EPO can still have a very significant impact on conventional breeding.

If this development is not stopped, continued legal uncertainty and ongoing legal challenges will make traditional plant breeding a highly complicated matter. Thus impacting the future of food and agriculture as well as the livelihoods of many people, including people from regions in the Global South. These risks could be further intensified and escalated by ongoing climate change.

A handful of large corporations could 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.

In the face of ongoing food crises due to climate change and wars, such as that in the Ukraine, as well as political instability in many regions, we should not allow property claims on biological diversity which will further hamper the breeding of our food plants. This will simply add another major threat to food security and food sovereignty.

Free the seeds! Save the future of our food!

The *No Patents on Seeds!* campaign aims 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.

This 'freedom to operate' is also the precondition for the future of

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

According to our analysis, there are three crucial areas that need to be changed to effectively implement current prohibitions in regard to patents on the conventional breeding of plants and animals:

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. Any usage of naturally existing genetic variations within the process of conventional plant breeding has to be excluded from patent claims.

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.

No Patents on Seeds! has started a petition calling for an international conference. The organisation is demanding that a ministerial conference of the contracting states (↗ „Glossary") of the EPO is held within one year, with the aim of taking effective measures to stop patents being granted on conventional plant and animal breeding. In addition to stopping patents on processes of crossing, selection, usage of naturally occurring genetic variations or random mutations, *No Patents on Seeds!* is also calling for a prohibition on extending the scope of patents granted on genetic engineering techniques to plants and animals derived from conventional breeding.

The controversies of 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), 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 4000 patents on plants and 2000 patents on animals have been granted in Europe, most of which are for genetic engineering.

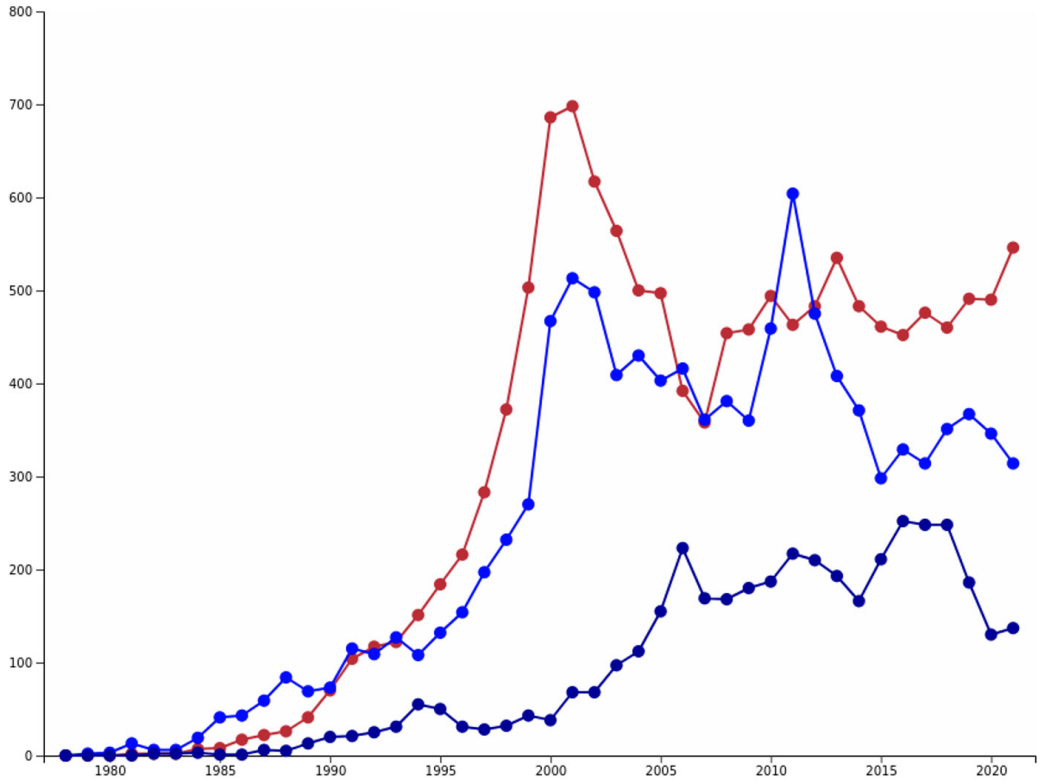

Figure 1: Patents on plants - number of patent applications filed for all plants under PCT/WIPO (upper /red line) and at the EPO (middle / blue line) as well as patents on plants granted by the EPO (lower line) per year. Research according to official classifications (IPC A01H or C12N15/82). Source: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

There is an alarming trend in patents being extended to conventional breeding: within the last ten years, around 100 new patent applications on conventional plant breeding in Europe were filed each year (via EPO or WIPO). Out of more than 1500 patent applications, nearly 300 patents have already been granted, even though patents on 'essentially biological' (non-technical) plant and animal breeding are prohibited in European patent law (Article 53(b), 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.

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

Every patent on conventionally derived traits can simultaneously impact the breeding of dozens or possibly over a hundred plant varieties.[2] Depending on the business strategy of the patent holder, they may require licenses or block access to biological resources.

It should be noted that these patents are not just limited to plants and seeds, they also cover the harvest, and, therefore, any food production using the harvest (grain, fruits, drinks, vegetables and meat). For example, in 2016, patents covering conventionally-bred barley and the beer made with the barley 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 or subsequent sale unless they have permission from the patent holder. Patents also create uncertainty: 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 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: the PINTO database[3], established by European Seed Association (ESA), shows that 103 granted European patents were listed in the database at the end of 2021, and the number of varieties affected by these patents was more than 850 (see also Table 1). Out of these, 129 varieties (such as sunflowers, maize and lettuce) are already covered by several (up to four) patents. Since the input to the database is voluntary, it is likely that several other patents covering conventional breeding are not listed, and have also not been made accessible via license fees.

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

3 Ibid.

Table 1: Overview of 10 examples of European patents already granted on 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 Bremia lactucae (downy mildew) resistance	Bejo Zaden	121
EP2515630	Genetic Markers Associated with Drought Tolerance in Maize	Syngenta	93
EP2451269	Plant resistant to a pathogen	Syngenta	56
EP1804571	PMMOV resistant Capsicum plants	Monsanto Invest	47
EP2464215	Methods for enhancing the production and consumer traits in plants	Syngenta	46
EP2464213	Methods for enhancing the production and consumer traits in plants	Syngenta	45
EP0921720	Aphid resistance in composites	Rijk Zwaan	38
EP1973396	Screening method for selecting plants that show a reduced wound-induced surface discolouration and plant and plant parts thus obtained	Rijk Zwaan	38
EP2586294	Peronospora resistance in Spinacia oleracea	Rijk Zwaan	38
EP1525317	Clubroot Resistant Brassica Oleracea Plants	Syngenta	36

A global perspective

Corporations, such as Bayer (Monsanto), Corteva (previously DowDupont/Pioneer), BASF and Chemchina/Syngenta, will become even more dominant if patents on plants and animals are not stopped. They already own more than 50 percent of the international seed market through acquisition of breeding companies from all over the world.[4] Moreover, they could shut down free access to biological diversity needed by other breeders if they 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 pig, poultry and cattle breeding markets.

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 overall number of plant patent applications filed 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).

The developments will also have consequences for the Global South, where many countries have adopted legislation to allow patents on seeds. Previous findings[5] indicated that 75 of the 126 countries in the Global South for which data were available, are ready to allow the patenting of plants, or parts thereof. Many such patents have already been identified. This could threaten food sovereignty in these countries as well as traditional regional production, propagation and seed exchange.

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

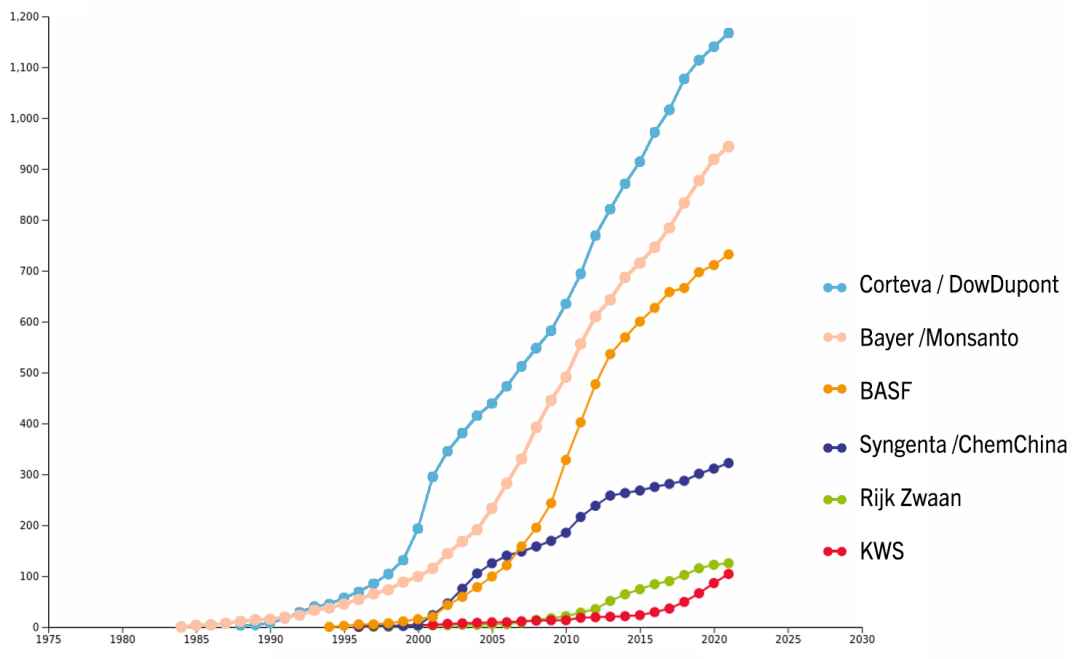

Figure 2: Patents on plants - number of patent applications for all plants under PCT/WIPO categorised by companies, per year, accumulated since 1990. Research according to official classifications (IPC A01H or C12N15/82). Source: www.kein-patent-auf-leben.de/patentdatenbank

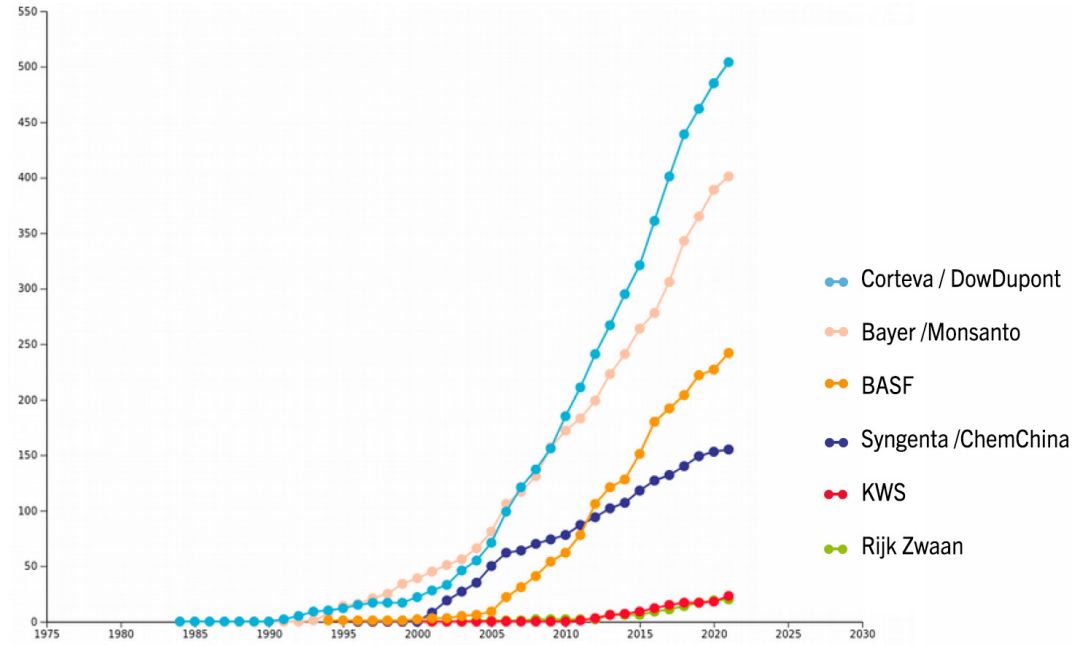

Figure 3: Patents granted on plants by the EPO, categorised by companies, per year, accumulated since 1990. Research according to official classifications (IPC A01H or C12N15/82). Source: www.kein-patent-auf-leben.de/patentdatenbank

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

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 the daily life of all people. 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, and also for the numerous organisations represented in the international coalition of *No Patents on Seeds!* It 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.

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 variants of genes 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.

The document (CA/56/17) reads: *"40. (…) 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. (…) 41. 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. Application of an exception to patentability cannot depend on hypothetical considerations and on whether specific process elements are traceable in the claimed product, in particular when taking into account the considerable developments in the technical field of plant breeding in the past and the unpredictable nature of future developments (…)."*

This legal loophole has had far reaching consequences. Companies now use specific wording in their patents to mix technical elements (such as use of CRISPR/ Cas) with standard methods of conventional breeding:

6 Commission Notice on certain articles of Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions C/2016/6997
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52016XC1108%2801%29&qid=1655109177515

7 European Parliament resolution of 10 May 2012 on the patenting of essentially biological processes
www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P7-TA-2012-0202+0+DOC+XML+V0//EN and
European Parliament resolution of 17 December 2015 on patents and plant breeders' rights
https://www.europarl.europa.eu/doceo/document/TA-8-2015-0473_EN.html?redirect

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

(1) Seeds, plants and harvested food derived from random processes and inheriting naturally occurring genetic variations are claimed as 'inventions'. (2) In many cases, additional 'technical toppings', such as genome editing or methods of transgenesis, are introduced but not necessary, they simply serve to blur the distinction between conventional breeding and genetic engineering.

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 by, for example, using CRISPR/Cas gene scissors.

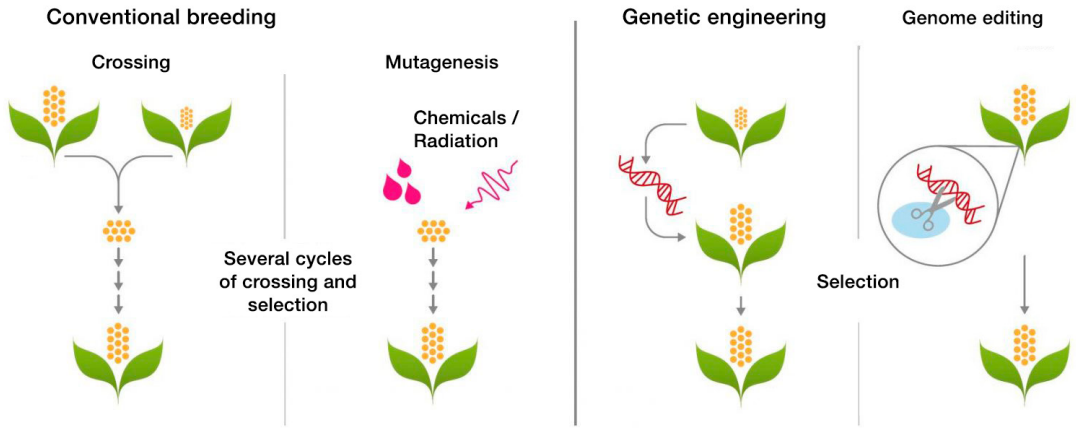

Figure 4: Differences between conventional breeding (including random mutagenesis) versus genetic engineering (including genome editing): conventional breeding always needs several cycles of crossing and selection to achieve to a desired trait, while GE can be used to directly insert new traits into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

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 genetic engineering methods, e.g. transgenesis or genome editing. Under these conditions, even seeds derived from conventional breeding could 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 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.

9 figure taken (and slightly adapted) from Genomxpress Scholae Nr 5, funded by the German Ministry for Education and Research (BMBF)

Research into patent applications covering conventional breeding and published in 2021

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).

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 several hundred patent applications. During 2021 (and similarly to the years before), around 300 patent applications were published covering plants and plant breeding, of which more than 100 applications cover conventional breeding.

Patents on plants with specific genetic variations

Patents on conventional breeding maybe categorized as those which only describe crossing and selection (the number of these patents decreased after the 2017 decision), and as those on random mutagenesis (provoking random mutations by physical and chemical means, followed by crossing and selection) which in 2021, made up around 10 percent of all patent applications. While most patent applications are not restricted to specific methods of plant production, around 10 percent claim selection methods.

Among the patent applications claiming whole plants (seeds, harvest), we found that a significant number (around 25 % of the patent applications on conventional breeding) are targeting plant genes, sometimes covering thousands of genetic variations. The companies claim all future uses of the genetic variations as well as all plants inheriting the particular genetic variations, regardless of how they will be bred.

In many cases, the patent applications claim genetic variations called 'single nucleic polymorphisms' (SNPs). These polymorphisms, which may be associated with favourable biological effects, can be found in all genes within each species. For example, SNPs can confer desired plant characteristics such as higher tolerance to plant diseases. The relevant genetic variations are frequently found in native populations that are crossed with the commercial varieties.

The patent applications are not restricted to specific methods of producing the plants. A typical claim wording is 'plants, seeds and fruits comprising specific nucleotides' or 'specific nucleotides conferring desired characteristics and all plants derived from selecting and breeding comprising it'.[10]

These patent applications represent a specific strategy for circumventing the existing prohibitions under Art. 53 (b): instead of claiming plants derived from specific techniques or methods, the claim includes all plants bred in future which inherit the desired genetic traits, regardless of the breeding method. In summary, the genes (their variations), their usages (such as for screening, crossing and selection, genetic engineering) and all resulting plants are claimed as inventions.

In awareness of the increasing number of patent applications in this category, we chose this as the focus of our research in 2021.

10 A similar case (WO2020239495 filed by BASF/ Nunhems) was already described in a previous report https://www.no-patents-on-seeds.org/en/publications/report2021

Table 2: Overview on examples for international patent applications on plant genes, published in 2021

Company	Number	Species	Goal
BASF/Nunhems	WO2021185774	cucumber	resistance to fruit rot
	WO2021213892	tomato	resistance to ToBRF-Virus
ChemChina/ Syngenta	WO20210000878 (EP3993610)	soy	resistance to rust
	WO2021030391	maize	resistance to ear rot
	WO2021154632	soy	resistance to Asian soy rust
	WO2021198186	vegetable and soy	resistance to nematodes
	WO2021260673	soy	resistance to pathogens
KWS	WO2021074367	plants	enhanced disease resistance
	WO2021093943	beet	resistance to nematodes
	WO2021116448	beet	cold resistance
	WO2021231467	maize	resistance to stalk root
Rijk Zwaan	WO2021110855	tomato	resistance to ToBRF-Virus
	WO2021116486	melon	resistance powdery mildew
	WO2021123429	solanaceae	resistance to torradovirus
	WO2021170850	melon / cucurbitaceae	resistance to CM-Virus
	WO2021180949	spinach	resistance to downy mildew
	WO2021255272	solanaceae / tomato	resistance to root knot nematode
	WO2021170868	tomato	resistance to ToBRF-Virus
Vilmorin	WO2021245435	melon	resistance to scab, aphids, mildew
	WO2021245282	tomato	resistance to ToBRF-Virus

Typically, the relevant genes are identified by so-called bioassays: in a first step, the plants are exposed to pathogens such as fungal diseases. The plants which show natural resistance to the disease are then used for gene analysis and further breeding. In most patents, the so-called 'technical process' is simply based on the selection of the plants and their use in further crossing and selection. In several cases, the language of the patents is confusing, making it difficult to understand to which extent conventional breeding was used to generate the plants. In many cases, the genes were first were detected in wild relative species which can be found in international gene banks. In other patent applications, the origin of the genes may also be from previously or currently marketed plant varieties. In summary, there is no clear distinction made between the origins of the genetic variations and the methods used to generate the plants.

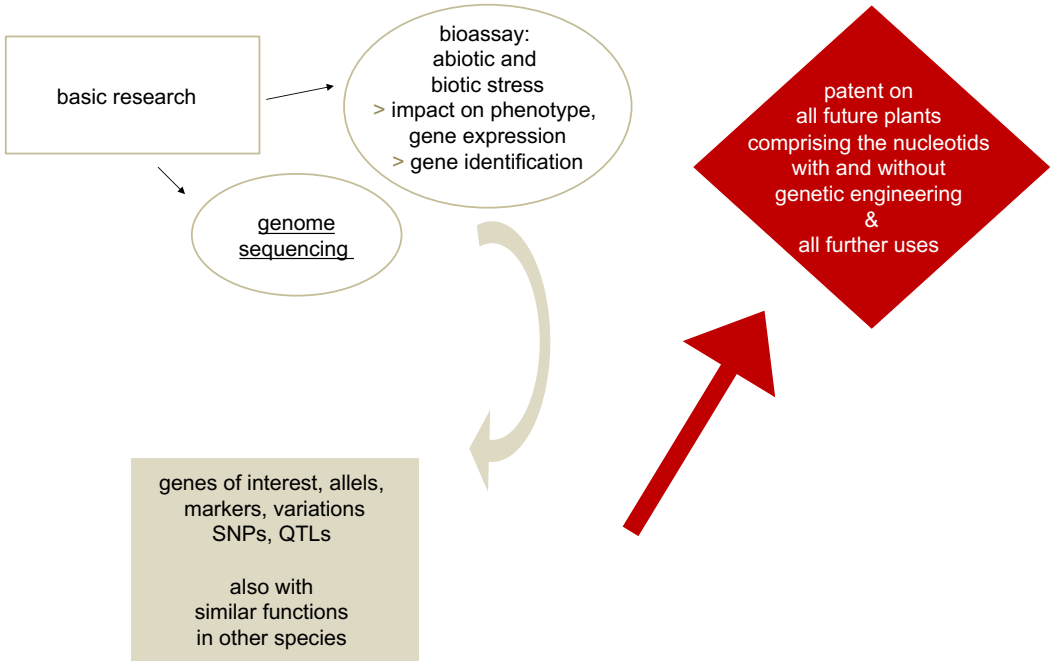

Figure 5: Overview of typical methods used and described in patent applications to identify genetic variations in plants with favourable biological effects, which can be claimed as 'inventions'.

Case study (1): barley & beer

Patent applications covering barley and beer describe random mutations used to generate genetic diversity, which were then used for further crossing and selection. The most recent patent application filed by Carlsberg in 2021, WO2021175786, is a typical example of the way in which companies are trying to create the impression of an 'invention': the plants exhibit random genetic variations. The claims in the patent cover all barley plants with described genetic variations, regardless of how they were achieved.

The use of the barley for brewing beer is also claimed in patent application WO2021175786: several types of beer are named (page 41 of the description), such as Altbier, Berliner Weisse, Blonde Ale, Dortmunder Export, Doppelbock, Hefeweizen, Helles, Kölsch, Pale Ale, Pilsener, steam beer, stout, lager, and also whiskey and vodka. Producing these beverages would be subject to patent rights if that specific barley is used.[11]

11 See also www.no-patents-on-seeds.org/en/patents_barley

Table 3: Patents on barley filed by Carlsberg, based on random mutations

International application (WIPO)[12]	EP number (EPO)	Content	Legal status
WO2005087934	EP1727905	Taste of the beer; claims covering barley and beer	grant intended
	EP2290089	Taste of the beer; claims covering barley and beer	Examination
	EP2305797	Taste of the beer; claims covering barley and beer	Withdrawn 2017
WO2010063288	EP2373154	Taste of the beer; claims covering barley and beer	Granted 2016 Opposition and appeal filed, maintained (T0420/19).
WO2010075860	EP2384110	Taste of the beer; claims covering barley and beer	Granted 2016 Opposition and appeal filed, revoked 2021
WO2011150933	EP2575433	Taste of the beer; claims covering barley and beer	Granted 2016 Opposition filed and rejected
WO2018001884	EP3478832	Methods for selection of barley plants (but no plants claimed as invention)	Granted 2022
WO2019129736	EP3731627	Changed quality of barley for brewing process; claims covering barley and brewing methods	Request for examination
WO2019129739	EP3731628	Changed quality of barley for brewing process; claims covering barley and brewing methods	Request for examination
WO2019134962		Changed quality of barley for brewing process; claims covering barley and brewing methods	Withdrawn
WO2021038003	EP3785529	Taste of the beer; claims covering barley plants and beer production method	Withdrawn (09.02.2022)
WO2021069614		Methods for mutagenesis and further breeding of barley	Not yet under examination
WO2021175786		Changed quality of barley for brewing process; claims covering barley and brewing methods	Not yet under examination

12 World Intellectual Property Organisation (WIPO); many of these patents also are examined by the EPO.

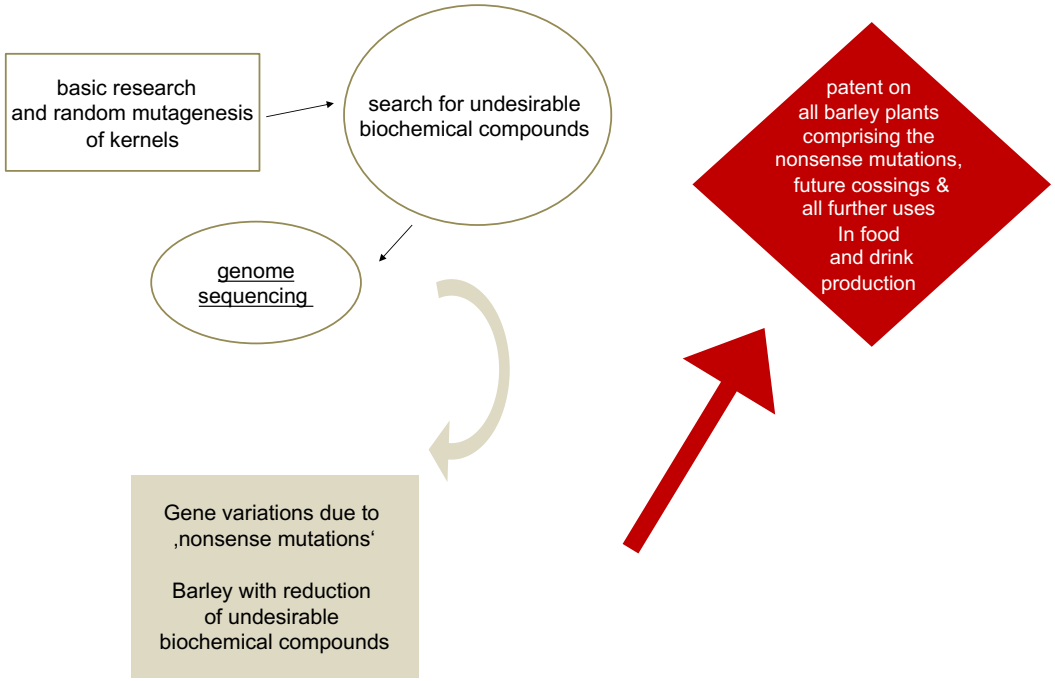

Figure 6: In the case of the Carlsberg patents, the kernels are exposed to chemical substances known to speed up the numbers of 'random' mutations. The resulting kernels are screened for concentrations of specific compounds. The genome of the grains which meet expectations are then analyzed. Barley plants which inherit favourable mutations are claimed as 'inventions'.

Case study (2): The Syngenta files

In other cases, many genes and variations of genes are claimed in specific species, such as soybeans or maize. For example, the Syngenta patent application, WO2021154632, claims genetic variations that were detected in glycine *tomentella*, a wild relative of soybean found in Asia-Pacific regions, such as Australia and China, which may confer disease resistance to Asian soybean rust.

The patent contains a description of how the genetic variations (single nucleotide polymorphisms, SNPs) can be introduced into soybeans by crossing, marker-assisted selection (MAS), genome editing or gene transfer. Around 5000 relevant genetic variations are listed and claimed as inventions in the patent. From these examples we can see that the genes were detected in wild populations of glycine *tomentella* which were exposed to Asian soybean rust (bioassay). The relevant genetic variations were then taken from the wild populations and introduced into domesticated varieties of soybean by crossing and selection.

All soybean plants which inherit the relevant genetic information are claimed as inventions if they show increased resistance to Asian soybean rust (ASR). All other usages of the gene sequences for screening and selection as well as any further breeding with the plants and genome editing, are claimed as part of the invention.

In effect, this creates major legal uncertainty which will affect other breeders. It would, moreover, be almost impossible to find out whether a soybean variety showing improved resistance to Asian soybean rust inherits any of the SNPs listed in the patent. Therefore, breeders can no longer use the existing plant varieties to create

new varieties. They cannot even make use of the wild populations of glycine preserved in various gene banks around the world for breeding, as all usage of the relevant genes are covered by patents. In effect, these patents are likely to become an impenetrable 'jungle' for all other plant breeders.

Syngenta/ChemChina filed several similar patent applications in 2021, covering thousands of genetic variations (SNPs) from food plants, such as soy and maize and vegetables, which occur naturally and can, for example, enhance resistance to plant pests (WO2021000878, WO202103391, WO2021154632, WO2021198186, WO2021260673).

Table 1: SNP Positions within SEQ ID NO: 1 that are associated with increased resistance to ASR

Table 1 is organized as follows: (Position in Scaffold 22052, favorable allele, unfavorable allele)

(24,A,G)(2425,G,A)(3023,T,C)(3024,C,T)(3094,A,C)(3158,A,G)(3666,G,A)(4104,C,A)(4133,
T,TTGCTGCTATAATCGATTAAGC)(4155,G,C)(4156,C,A)(4157,T,C)(4159,C,G)(4160,T,
G)(4239,C,A)(4289,A,G)(4321,C,T)(4355,C,T)(4474,G,T)(4528,C,T)(4659,A,C)(4820,T,C)(4
906,T,G)(5028,T,G)(5077,T,C)(5202,A,C)(5228,G,A)(5254,G,A)(5291,T,C)(5316,G,A)(5613,
G,A)(5649,T,C)(5744,C,T)(5755,T,TGGGTCATGGC)(5758,GACAACA,G)(6029,A,C)(6133
,C,T)(6183,T,A)(6210,A,ACT)(6599,T,C)(6695,G,A)(6931,T,TG)(6937,C,T)(7007,T,C)(7030
,A,G)(7094,A,G)(7117,T,TA)(7322,T,C)(7467,A,G)(7530,G,C)(7558,G,A)(8071,A,G)(8367,
A,G)(8524,T,C)(8691,T,G)(8729,A,C)(8877,G,A)(8913,G,T)(9001,A,ATG)(9005,A,G)(9007,
G,A)(9008,G,C)(9010,A,T)(9199,T,A)(9311,C,T)(9447,T,C)(9568,A,G)(9595,T,C)(9648,T,A)
(9871,A,AC)(9896,T,A)(9911,C,T)(10105,C,T)(10319,C,T)(10443,A,G)(10487,A,C)(10497,
A,G)(10567,T,C)(10738,A,C)(10914,G,T)(10945,T,A)(11114,A,C)(11134,C,A)(11155,G,T)(1
1219,A,G)(11272,C,T)(11869,A,G)(11975,AT,A)(12370,C,T)(12403,C,T)(12474,C,T)(12567,
G,C)(12734,G,A)(12997,C,A)(13052,A,G)(13071,G,A)(13101,C,T)(13103,A,G)(13174,C,A)(
13210,C,G)(13257,C,G)(13430,A,G)(13474,T,C)(13589,G,C)(13823,A,C)(13943,TA,T)(1409
3,A,G)(14246,C,T)(14277,G,A)(14303,A,C)(14337,G,A)(14877,T,G)(14907,T,C)(14926,A,G)
(15061,C,T)(15405,A,G)(15525,A,C)(15722,T,C)(15783,C,A)(15809,A,T)(15907,ATGCATA
GT,A)(15991,G,A)(16377,A,T)(16418,A,G)(16437,A,G)(16590,G,A)(16695,T,C)(16725,A,C
)(16729,A,T)(16951,C,T)(17006,T,C)(17302,G,A)(17588,G,A)(17679,G,A)(18002,A,G)(1862
0,G,T)(18631,A,G)(18673,C,T)(19024,G,T)(19060,G,A)(19260,G,A)(19349,G,A)(19535,C,A
)(19559,T,C)(19693,T,C)(19773,A,C)(19830,A,G)(20155,A,G)(20235,T,G)(20382,C,T)(2046

Figure 7: Table from patent application WO2021154632 listing the SNPs which are part of the invention: in each bracket a favourable variations (allele) is given at a specific position in the genome which may help to increase plant resistance to Asian soybean rust. The overall number of claimed genetic variations is around 5000 SNPs.

Case study (3): Over-patenting of tomatoes

The Tomato Brown Rugose Fruit Virus (ToBRFV or TBRFV) is a plant virus that was first described in 2015 in Jordan and Israel, it has been spreading rapidly ever since. It mostly affects tomato and pepper plants, and takes its name from the wrinkly spots (rugose) on fruits. Five patent applications on tomatoes with resistance to the pathogen were published in 2021. As further research showed, around a dozen international patent applications covering ToBRFV-resistant tomato plants had already been filed by BASF (Nunhems), Bayer (Seminis), Enza Zaden, Philoseed, Rijk Zwaan and Vilmorin, and published in the time period from 2018 to the end of 2021. In most cases, the relevant genetic variations were detected in wild relatives (such as *S. pimpinellifolium*, originating from Peru/Chile) of domesticated tomatoes.

The companies claim various genomic regions identified on the chromosomes of tomatoes. For example, chromosome 11 of the tomato is targeted by ten different patent applications from five companies (such as Bayer/Seminis, BASF/Nunhems and Rijk Zwaan), claiming similar genomic regions and also genetic combinations, some of which overlap. All future tomato plants inheriting these genetic variations are claimed as invention, regardless of the method of breeding.

This case of 'over-patenting' is likely to effectively block access to the biological material needed by all breeders to generate the desired virus-resistant plants: conventional breeders trying to produce tomato varieties and, at the same time, avoid patent infringement, would have to analyse around a dozen patent applications and screen for all genetic variations described in the patent. They may, in addition, possibly have to acquire around a dozen license contracts. In many cases, the breeders will also come to the conclusion that they cannot develop the tomatoes without incurring fees for expensive patent attorneys and comprehensive laboratory analyses. Legal uncertainty and the threat of expensive legal battles are thus likely to prevent breeders from generating the desired tomato varieties, maybe with the exception of a few large companies.

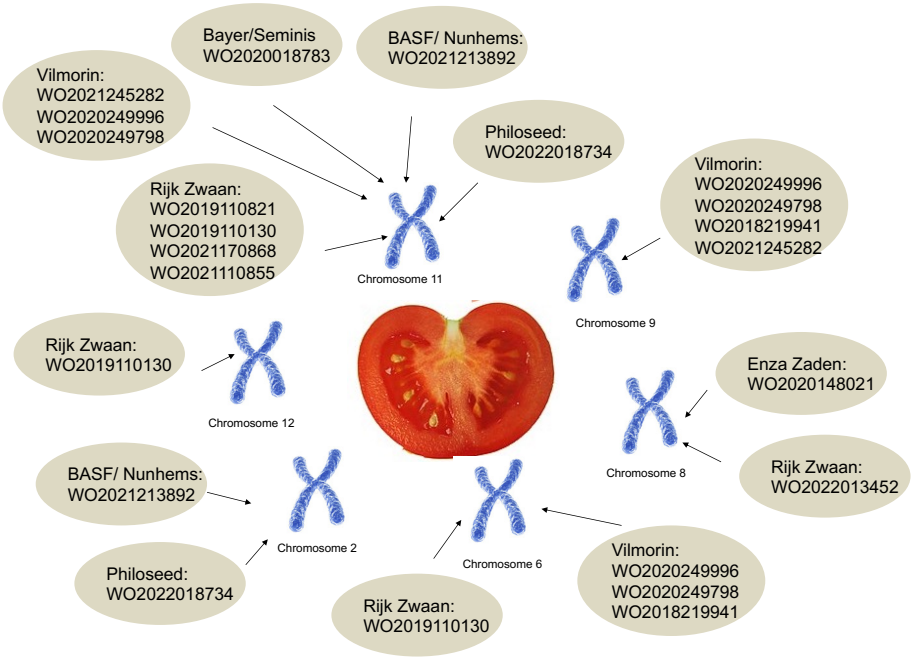

Figure 8: Patent applications filed by various companies on breeding tomatoes with resistance to Tomato Brown Rugose Fruit Virus (ToBRFV). Several companies are claiming various genomic regions identified on the chromosomes of tomatoes, some of which overlap. This kind of over-patenting is likely to hamper or even block the breeding of tomato varieties with the desired resistance.

Research into European patents covering conventional breeding granted 2017-2022

Several patents were granted on conventionally-bred plants in 2021, e.g. on tomatoes with drought tolerance or a longer shelf life, melons with bushy growth, cucumber with compact growth and lettuce with virus resistance. All the plants are claimed based on the specific genetic variations they comprise. In addition to granting these new patents, an appeal against a patent granted to Carlsberg was rejected, thus confirming the current practice in regard to a decision of the Technical Board of the EPO (see Table 3, EP2373154, T0420/19).

As described in previous chapters, the genes of interest were detected via bioassays or phenotypic analysis, such as growth habit. All kinds of breeding activity involving these genes are claimed, e.g. screening and selection with markers, crossing or random mutagenesis. Genetic engineering and transgenesis are mainly introduced as technical toppings to create the impression of technical inventions. However, in essence, the decisive method in generating the plants in all cases was conventional breeding.

Table 4: Examples for granted European patents on conventionally bred plants in 2021

Number Company	Title	Content & Comment
EP2814316 BASF/Nunhems	Triploid watermelon plants with a bush growth habit	Watermelons (plants, fruits) which is triploid and comprises three genetic variations which contribute to a bush growth habit, derived from any kind of breeding activity.
EP2440664 BASF/Nunhems	Drought tolerant plants	Tomatoes comprising genes which were identified to be active under drought conditions, derived from any kind of breeding activity (see case study below).
EP3094722 Enza Zaden	Phytophtera resistant plants belonging to the Solanaceae family	Solanaceae plants (tomatoes, potatoes) which comprise at least a combination of two genes, originally detected in petunia and tobacco and introduced into vegetable plants, for example, by random mutagenesis.
EP3167051 Enza Zaden	Phytophtera resistant plants belonging to the Solanaceae family	Solanaceae plants (sweet pepper) which comprise at least a combination of two genes, originally detected in petunia and tobacco and introduced into sweet pepper plants, for example, by random mutagenesis.
EP 2219433 BASF/Nunhems	New cucumber plants with a compact growing habit	Cucumber plants (seeds, fruits) which comprise marker genes used for the selection of a compact growth, derived from any kind of breeding activity.
EP 2900817 BASF/Nunhems	Solanum Lycopersicum plants having non-transgenic alterations in the ACS4 gene	Tomato plants (seeds, fruits) which comprise genetic variations which cause delayed ripening, derived from any kind of breeding activity.
EP 2966993 Rijk Zwaan	Tomato spotted wilt virus and/or impatiens necrotic spot virus resistance in cultivated lettuce	Lettuce plant (seeds) which comprise marker genes which are associated with disease resistance against virus pathogens, derived from any kind of breeding activity.

These examples show that the EPO has so far simply ignored the differences between conventional breeding and genetic engineering. Patents are granted on all plants inheriting specific genetic variations, which may have been generated from random mutagenesis or from other breeding practices. This completely undermines and exempts the existing prohibitions in patent law, which only allows the patenting of technical inventions and excludes patents on conventional (essentially biological) breeding.

As seen in patents that have already been granted, the wording is often confusing, making it difficult to understand the extent to which conventional breeding was used to develop the plants. In many cases, the genes were first detected in model plant species, such as Arabidopsis or wild relative species. In addition, previously or currently marketed plant varieties may have been used as a source. In summary, no clear distinction is made between the origin of the genetic variations and the method used to generate the plants.

Around a dozen such patents were granted in Europe in 2021, all following the same strategy of developing and claiming the plants. As research on patent applications published in 2021 shows, these patents are likely to be just a few examples of many other patents which will be granted in near future, and which will undermine free breeding guaranteed by breeder's exemption under PVP law.

The genetic information claimed as an invention in the patents can block any further use of the genetic information to breed and market new varieties. This is hugely concerning especially for conventional breeders, but the patents are also likely to heavily impact applications of New GE, e.g. CRISPR/Cas. Companies actively engaging in genetic engineering will also be affected: if SNPs are patented, they can no longer be used without permission as a template to direct where gene scissors, such as CRISPR/Cas, cut. It will not simply be access to the technology that is blocked by patents, but also to the genetic diversity needed to apply tools such as CRISPR/Cas.

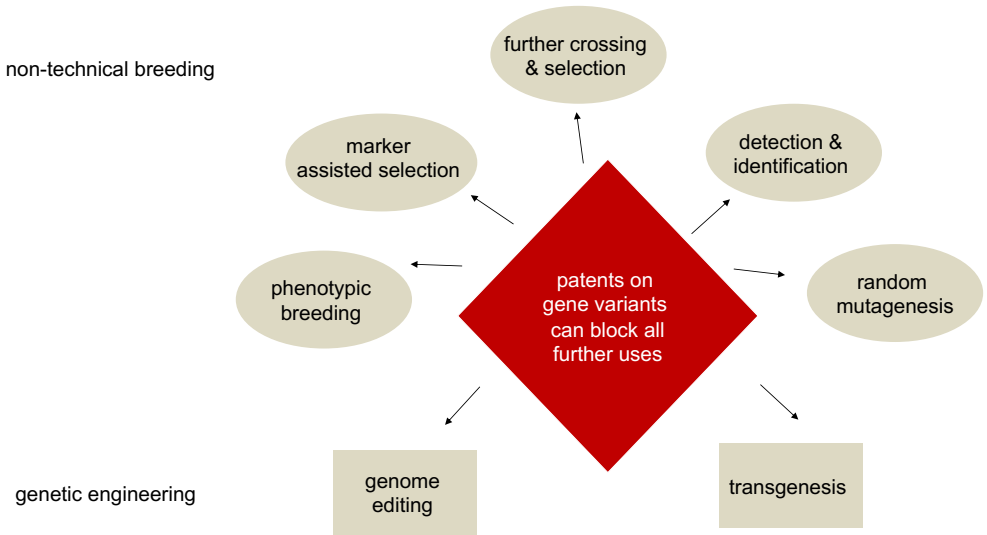

Figure 9: Patents on plant genes can block all further uses of plants and genes, especially for breeding and marketing of new varieties.

Case study (1): One naturally occurring gene – seven patents granted

The patent strategy as applied in 2021 could already previously be exemplified by patents granted for Enza Zaden in 2017 and 2018: Genes which can confer improved resistance to downy mildew (a fungal disease) were discovered in a model plant (Arabidopsis). Based on these findings, Enza filed seven patent applications on food plant species which inherit similar genetic characteristics after being subjected to random mutagenesis: In result, Enza Zaden, with the help of the EPO, was able to turn one naturally occurring genetic variation into seven valid European patents on onions, tomatoes, potatoes, soy, cucumber, grape vine and melons.

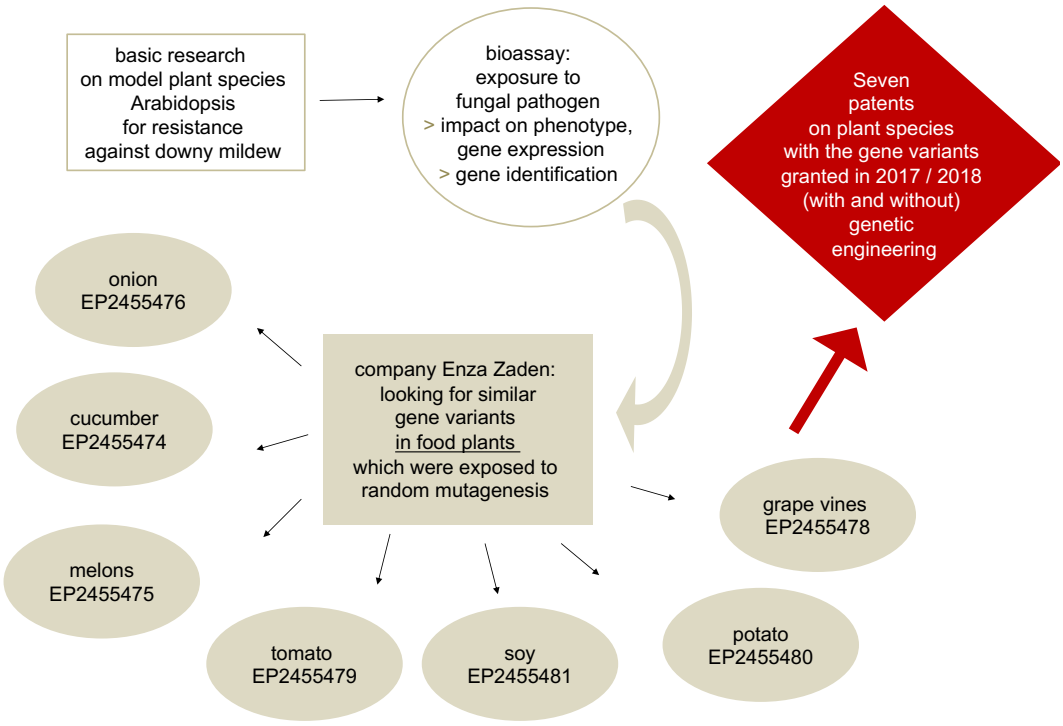

Figure 10: European patents on plants with genes which can confer improved resistance to downy mildew, granted for Enza in 2017 and 2018.

Case study (2): Tomato with drought resistance

A recent example of how the EPO is using legal loopholes to grant patents on conventionally-bred plants is EP 2440664, which was issued in April 2022 to BASF/ Nunhems. It claims tomato plants with an improved drought tolerance as well as their fruits and seeds. The relevant genetic information was originally detected in wild (non-domesticated) populations.

As described in the patent: *„[0114] The mutant allele is in one embodiment generated or identified in a cultivated plant, but may also be generated and/or identified in a wild plant or non-cultivated plant and then transferred into a cultivated plant using e.g. crossing and selection (…). Thus, a mutant SlPP2C1 allele may be generated (human induced mutation using mutagenesis techniques to mutagenize the target SlPP2C1 gene or variant thereof) and/or identified (spontaneous or natural allelic variation) in other Solanum species including for example*

S. cheesmanii, S. chilense, S. habrochaites, S. chmielewskii, S. lycopersicumxS. Peruvianum, S. glandulosum, S. hirsutum, S. minutum, S. parviflorum, S. pennellii, S. peruvianum, S. peruvianum var. Humifusum and S. pimpinellifolium, and then transferred into a cultivated Solanum plant, e.g. Solanum lycopersicum by traditional breeding techniques. The term "traditional breeding techniques" encompasses herein crossing, selfing, selection, double haploid production, embryo rescue, protoplast fusion, etc. as known to the breeder, i.e. methods other than genetic modification by which alleles can be transferred."

As a result, the patent covers all plants with the desired characteristics, regardless of whether they were derived from conventional breeding or genetic engineering.

Climate change poses huge challenges, including the question of how to adapt our food plants. Against this backdrop, access to biological diversity which is needed for future breeding must not be controlled, hampered or blocked by patents. Such patents threaten our livelihoods.

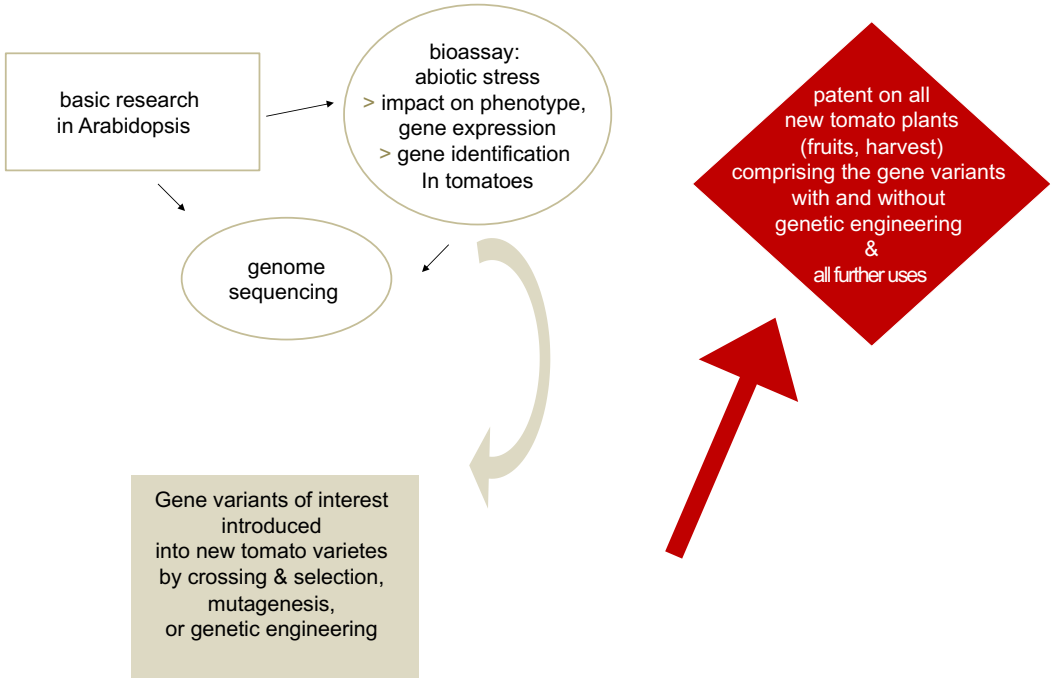

Figure 11: European patent on tomatoes with genes which can confer improved drought tolerance granted to Nunhems in 2021.

Case study (3): One patent claiming more than 100 varieties

In April 2022, the EPO announced that they would grant patent EP2961263 to Bejo Zaden. It claims lettuce (*Latuca sativa*) which inherits genes from a wild relative Latuca species that can improve resistance to downy mildew. The plants are derived from crossing and selection. According to the PINTO database (see Table 1), the patent concerns more than 100 plant varieties.

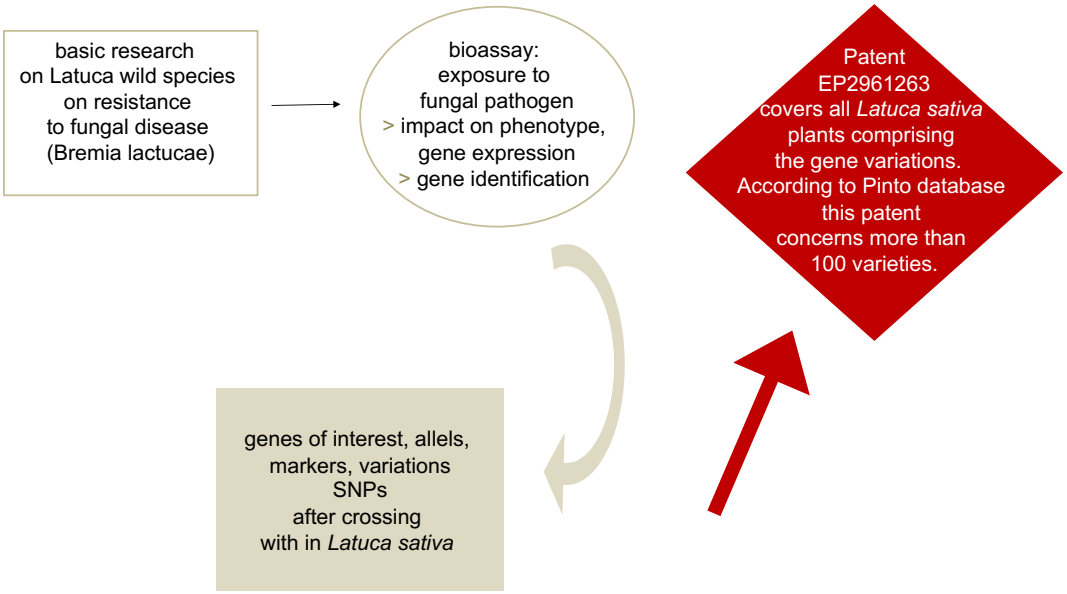

Figure 12: Patent to be granted on lettuce to Bejo Zaden. The patent concerns more than 100 varieties.

Case study (4): Maize not so easy for breeders to digest

In June 2022, a patent was granted to the German company, KWS, (Kleinwanzlebener Saatzucht). EP3560330 covers maize with improved digestibility. The patent claims the plants, regardless of whether they are derived from random mutations or genetic engineering. In addition, it claims the usage of naturally occurring gene variations for screening and selecting the plants within the process of conventional plant breeding. As shown in the description, the respective gene variants were detected in existing maize plants, stemming from conventional breeding. The KWS can now control future production of plants derived from randomly mutated genes, and thus prevent other breeders from using the naturally occurring genes in conventional plant breeding.

This patent sets a precedent: it is the first patent to be granted on a patent application filed after July 2017. In accordance with the G3/19 decision, Rule 28(2) had to be applied in this case. Under these conditions, the examination guidelines of the EPO request that a so-called 'disclaimer' is inserted (under Rule 28(2)) to exclude plants derived from essentially biological processes from falling within the scope of the patent. The disclaimer was introduced (in Claim 3), but it only has a limited effect: the patent still covers randomly mutated plants and the usage of genetic variations for the screening and detection of plants within the process of conventional plant breeding. Thus the patent as granted is not confined to genetic engineering, but also impacts conventional breeding of the respective plants.

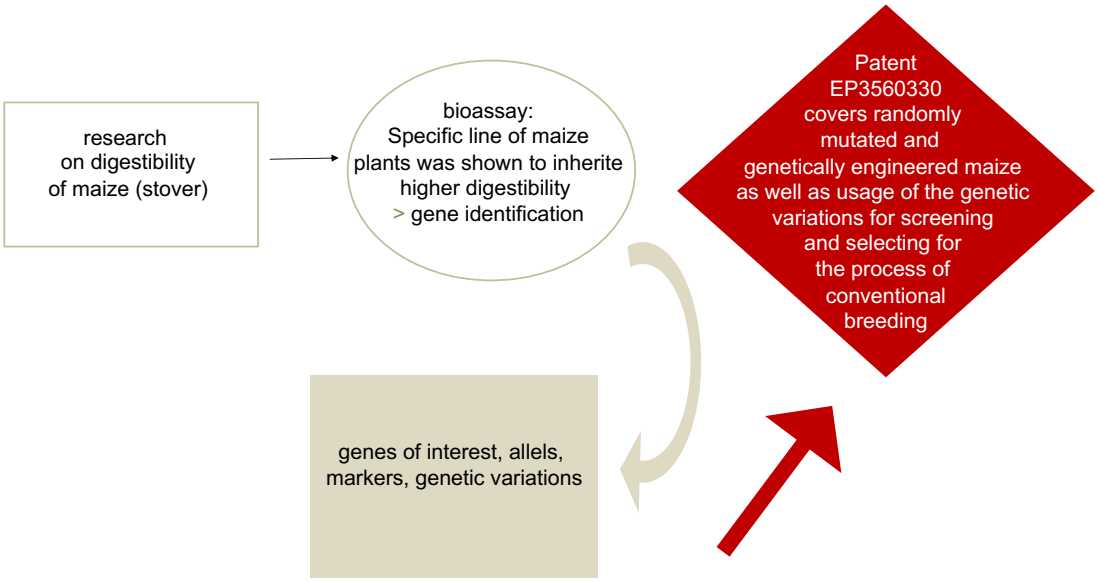

Figure 13: European patent EP 3560330 on randomly mutated maize and usage of naturally occuring genetic variations for the processes of plant coventional breeding, granted in 2022 (with disclaimer)

The legal situation

The EU patent directive 98/44 EC is decisive in this context. This EU regulation was integrated in the Implementing Regulations of the European Patent Convention (EPC), which is binding for the decision-making of the EPO.

As can be concluded from Recitals (1, 2, 52, 53) and Art.16, the directive addresses the technical developments in the context of genetic engineering. There is an historical reason for this: before the directive came into force, the EPO had stopped granting patents on genetically engineered plants and animals (T356/93). This led to a sharp increase in pressure from companies wanting to claim genetically engineered organisms as their inventions. Therefore, the EU directive can be seen as a response to this situation. However, at the same time, the EU directive does not provide any indication that the EU actually wanted to allow patents on conventionally-bred plants and animals.

There are two crucial legal provisions in the EU directive which are relevant in this context:

a. The directive only allows patents on technical inventions which concern plants and animals. For example, Art. 4 (2), allows patents on inventions which are *"not confined to a particular plant or animal variety"*. This addresses the possibility of transferring isolated genes from one organism to another using genetic engineering techniques. At the same time, Art. 4 (1) of the EU directive as well as Art. 53 (b) of the EPC prohibit patents on conventional ('essentially biological') breeding of plants and animals.

b. Art. 3 (2) of the EU directive allows patents on "biological material which is isolated from its natural environment or produced by means of a technical process (…) even if it previously occurred in nature." This article, for example, allows patents on genes isolated from the human body (see also Art. 5 of the directive). At the same time, a plant gene in a plant cell, a plant species or a family of plant species (which can be crossed with each other), cannot be considered as 'isolated from its natural environment'. As shown in recent case law, the EPO grants patents on the usage of naturally occurring genetic variations within the process of conventional breeding. Consequently, access to the plants and animals naturally inheriting those genes is hampered. The EPO ignores that, in the context of plant and animals, there are specific provisions, such as Art. 4 of the EU directive and Art. 53(b), EPC), that make it necessary to restrict the scope of patents to technical inventions.

While the examination guidelines of the EPO state that "thus transgenic plants and technically induced mutants are patentable, while the products of conventional breeding are not", EPO practice shows the opposite is true. What is largely missing is a meaningful distinction between technical processes (such the targeted insertion of a new trait) and essentially biological processes (such as usage of random mutations and genetic variations within conventional breeding).

However, biotech industry patents claim all usages of genetic variations identified in plants and animals, including all plants and animals derived from breeding activity which inherit the genes. They ignore that, in context of plant and animals, there are specific provisions, such as Art. 4 of the EU directive and Art. 53(b), (EPC) that make it necessary to restrict the scope of patents to specific technical applications.

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"

The Enlarged Board of Appeal issued its decisions G2/07 and G1/08, which provide a definition of 'essentially biological processes' for plant and animal breeding (non-patentable), in order to distinguish them from technical inventions (patentable). It used 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. Keeping the different breeding categories explained above (Figure 4) in mind, there is no doubt that methods of conventional breeding (crossing and selection with and without mutagenesis) are excluded from patentability under Art. 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 accordance 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 which directly intervene in the genome of plants and animals are regarded as patentable. The EU Parliament[14] and the Council of the EU Member States[15] take the same view.

13 Commission Notice on certain articles of Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions C/2016/6997
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52016XC1108(01)

14 European Parliament resolution of 10 May 2012 on the patenting of essential biological processes
www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P7-TA-2012-0202+0+DOC+XML+V0//EN and
European Parliament resolution of 17 December 2015 on patents and plant breeders' rights
https://www.europarl.europa.eu/doceo/document/TA-8-2015-0473_EN.html

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

However, in preparation for the implementation of the 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 our report, 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 light of the legal analysis provided and the history of the decision in regard to Rule 28(2), this is unacceptable for traditional breeders, farmers, patent applicants as well as for *No Patents on Seeds!*

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 emanate 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.[17] 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 Art. 53(b) and Rule 28(2).

In addition, legal clarification is needed that genes in a cell, a species or a family of species (which can be crossed with each other), cannot be considered as 'isolated from its natural environment' in the sense of Art. 3 (2) of the EU directive that allows patents on *"biological material which is isolated from its natural environment or produced by means of a technical process (…) even if it previously occurred in nature."* Any usage of naturally existing genetic variations within the process of conventional plant breeding has to be excluded from patent claims.

3. Limiting the scope of protection

As evidence presented in this report 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 genetic variations. In several cases, patent claims in patents filed on plants derived from GE techniques (involving, for example, CRISPR/Cas) may also be extended to plants or animals if they have similar characteristics but are derived from conventional breeding.

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 Art. 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)

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

17 https://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_ii_5_5_1.htm

sharing the same characteristics obtained through "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 claims of patents granted by the EPO, which might help in some cases. However, doubts remain as to 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.

The problem is already recognized in national laws, such as the biodiversity law in France. It requests that the *"protection conferred by a patent on a biological material possessing specific characteristics as a result of the invention shall not extend to biological materials possessing those specific characteristics, obtained independently from the patented biological material and through essentially biological process, neither to biological materials obtained from the latter through propagation or multiplication"*[18] However, this may not be yet a solution for European patents validated in other countries.

Therefore, we are asking for other solutions to be developed which take the general difference between claims on the processes and claims on the products into consideration. In the context of Art. 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 Art. 53(b) effective, the scope of patents should be restricted to the technical process used to produce plants or animals.[19] This demand is in accordance with the wording of the EU Directive which only allows for technical inventions concerning plants and animals.

Now is the time to act!

Over a time period of ten years, around 100 patent applications were filed for conventionally-bred plants each year. 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 large corporations that can control access to biological resources needed for further breeding.

Due to legal uncertainty, political controversy 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.

The *No Patents on Seeds!* campaign aims to continue safeguarding '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.

18 LOI n° 2016-1087 du 8 août 2016 pour la reconquête de la biodiversité, de la nature et des paysages, Article 10: https://www.legifrance.gouv.fr/jorf/article_jo/JORFARTI000033016254

19 For further explanations, see the *No Patents on Seeds!* report (2018): https://www.no-patents-on-seeds.org/sites/default/files/2018-06/Report_No%20patents%20on%20broccoli,%20barley%20and%20beer_2018.pdf

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. Any usage of naturally existing genetic variations within the process of conventional plant breeding has to be excluded from patent claims.

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. This should be done in a meeting of the ministers of the contracting states of the EPO in accordance with Article 4a of the European Patent Convention.[20]

If this is not feasible, a change in the EPC can be decided by a Conference of the Contracting States. 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 conventionally-bred plants and animals from patents.

Both options 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.

20 https://www.no-patents-on-seeds.org/en/petition

Annex:

1. 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 interest of the biotech industry in obtaining patents on technical inventions. Patents are abused to claim biological resources and to turn living beings into patented products.

2. New problems arising from the EU Unitary Patent

The situation will become even more pressing for several European countries in the next few years, when most of the 27 member states of the EU become part of what is called the Unitary Patent (UP) (↗ „Glossary") system.[23] 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 group (Czech Republic, Hungary, Poland and Slovakia) or Austria 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 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, the system is expected to come into effect at the end of 2022 or beginning of 2023.[24]

21 www.businesseurope.eu/
22 https://patentepi.org/de/
23 https://www.unified-patent-court.org/about
24 https://www.consilium.europa.eu/en/documents-publications/treaties-agreements/agreement/?id=2013001

3. Are gene patents biopiracy?

Whether the access and use of a genetic resource is unlawful can only be answered by knowing the nature of the access and the donor country. Simplified, in the case of genetic resources for food and agriculture, one can assume two scenarios that can lead to a form of biopiracy in this sense.The Nagoya Protocol and the International Treaty on Plant Genetic Resources, among others, play an important role here.[25]

1. Access through a gene bank under a Standard Material Transfer Agreement (SMTA) of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA).
The ITPGRFA, and in particular the multilateral system of access and benefit-sharing (MLS) integrated therein, pursue the goal of facilitating access to genetic resources for plant breeding. The vast majority of member states of the European Patent Convention have also ratified the ITPGRFA. The MLS, as well as the Standard Material Transfer Agreement (SMTA) based on it, requires that *"Recipients shall not claim any intellectual property or other rights that limit the facilitated access to the plant genetic resources for food and agriculture, or their genetic parts or components, in the form received from the Multilateral System".* The Dutch Gene Bank (CGN) has stated in a note concerning patents on native traits that *"The interpretation of the claims mentioned above may be that the patents cover all use of the genes encoding for the traits described. These genes have been identified in and occur in CGN accessions. As a result, in such interpretation, enforcement of a patent such as mentioned above may be in conflict with the obligations of a recipient if that recipient has accepted the terms and conditions of the SMTA in order to obtain the accession."*

This means that

- The patents on gene sequences mentioned here are contrary to the principles of the International Treaty on Plant Genetic Resources.
- However, a violation of rights could only be claimed if an SMTA is signed when accessing the genetic resources. If a user violates his obligations under the SMTA, this may very well qualify as biopiracy, the unlawful appropriation of genetic resources.
- However, this potential infringement often cannot be proven because the vast majority of patent specifications do not disclose the exact origin of the resource.

The fact is that the patents on gene sequences mentioned here will make the facilitated access to genetic resources for breeding much more difficult - and thus undermine the intention of the International Treaty. This development is particularly detrimental to countries in the Global South and to farming communities, which

25 The Nagoya Protocol on Access and Benefit-Sharing, was negotiated within the framework of the Convention on Biological Diversity, to regulate access to genetic resources and the fair and equitable sharing of benefits arising from their utilisation. It supports therefore the implementation of the third objective of the Convention on Biological Diversity. The protocol was adopted on 29 October 2010 in Nagoya, Japan and entered into force on 12 October 2014. So far, it has been ratified by 134 parties (including the European Union). The objective of the Protocol is the fair and equitable sharing of the benefits arising from the utilisation of genetic resources, including by appropriate access to genetic resources. The Nagoya-Protocol clarifies that "Where a specialized international access and benefit-sharing instrument applies […]. this Protocol does not apply for the Party or Parties to the specialized instrument in respect of the specific genetic resource covered by and for the purpose of the specialized instrument." Such a 'specialized instrument' is the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) adopted by the Conference of the Food and Agriculture Organization of the United Nations on 3 November 2001. Thus far, the ITPGRFA has 149 Contracting Parties (including the EU). The Multilateral System of the Treaty facilitates access to the genetic materials under the management and control of the Contracting Parties to 64 crops for research, breeding and training for food and agriculture.

have largely developed these resources and make them available. They themselves do not file such patents - but they can be hindered in their use by the patents.

If access is through a gene bank and no SMTA has been signed, it is still possible that access, use and patenting may violate the ABS legislation of the original country of origin. For reasons of space, this scenario will not be discussed in more detail here.

2. Access through the collection of wild plants or unregistered landraces (without SMTA).
This scenario has been described in detail in the European Commission's guidance on the scope of application and core obligations of the EU ABS Regulation (2021/C 13/01):

"(Plant breeding) Use of a crop wild relative, landrace or farmer's variety in a breeding programme: A plant breeder accesses a crop wild relative in situ or a landrace or farmer's variety (20) from farmers' fields and uses this material in a breeding programme to introduce useful traits in commercial breeding materials. A breeding activity using such material (in scope of the EU ABS Regulation) is considered utilisation in the meaning of the EU ABS Regulation. Due diligence obligations therefore apply. The user needs to submit a due diligence declaration when a new variety is registered or placed on the market."

Due diligence means that the user must ascertain, *"that genetic resources and traditional knowledge associated with genetic resources which they utilise have been accessed in accordance with applicable access and benefit-sharing legislation or regulatory requirements [of the provider country], and that benefits are fairly and equitably shared upon mutually agreed terms, in accordance with any applicable legislation or regulatory requirements"* (Article 4.1 of the EU Regulation).

Research into the trait of a gene sequence for use in a breeding program is therefore a use within the meaning of the Convention on Biological Diversity, the Nagoya Protocol and the EU Regulation. Such use is therefore subject to the rules of the Convention on Biological Diversity and the Nagoya Protocol and the relevant laws implementing them at national level. Any research to apply for a patent that violates these rules can thus be called biopiracy.

Due to the lack of disclosure of origin, infringements are covered up.
In many of the patent applications we have examined, the exact origin of the genetic resource from which the gene sequence with the patented properties was taken remains unclear. Because of this lack of disclosure, patent applicants can obtain patents that violate national law of the donor countries and international law. The European patent system thus becomes an accessory to biopiracy. It does not check whether the intellectual property rights it grants were made possible by unlawful access to genetic resources.

4. The effects of disclaimers and the definition of essentially biological processes

In June 2017, the Administrative Council of the European Patent Office (EPO) decided that patents on conventionally-bred plants and animals would no longer be granted: the new Rule 28(2) was introduced into the Implementing Regulations of the European Patent Convention. At the same time, the EPO examination guidelines requested that a disclaimer should be used to exclude plants and animals derived from essentially biological processes. The examination guidelines state that "if a technical feature of a claimed plant or animal, e.g. a single nucleotide exchange in the genome, can be the result of both a technical intervention (e.g. directed mutagenesis) and an essentially biological process (a natural allele), a disclaimer is necessary to delimit the claimed subject-matter to the technically produced product." On the other hand the guidelines also state: "Both targeted mutation, e.g. with CRISPR/Cas, and random mutagenesis such as UV-induced mutation are such technical processes." These statements appear to be contradictory and create legal uncertainty in regard to the patentability of patents, such as WO2021154632 (page 20). It is not clear how the SNPs described in the patent could, for example, be distinguished from those triggered by sunlight (UV-induced mutations). In many cases, if screening is used to identify random mutations and gene variants, it will be impossible to identify the exact process which led to their emergence. This is, however, not the case if a trait is introduced in a targeted way using technical means, and where only those traits (originally) derived from such technical interventions are covered by patents.

While the examination guidelines also state that "thus transgenic plants and technically induced mutants are patentable, while the products of conventional breeding are not", a meaningful definition of essentially biological processes (conventional breeding) is lacking. Instead, document CA/56/17, which is used to interpret Rule 28 (2), appears to intentionally confuse the relevant differences between genetic engineering and conventional breeding (see also page 14). Thus, if a disclaimer is added,, this will not prevent patents on conventionally bred plants. What is largely missing is a meaningful distinction between technical processes (such as the targeted insertion of a new trait) and essentially biological processes (such as random mutations and gene variants in conventional breeding).

In addition, the Enlarged Board of Appeal, i.e. the highest legal body of the EPO, declared in its G3/19 decision that Rule 28(2) (and the disclaimer) would only be applied to patent applications filed after 1 July 2017. Therefore, in regard to Rule 28(2), there is very little existing case law. Prior to decision G3/19 being started, several patents were granted and approved under Rule 28(2) between July 2017 and the end of 2018. After that, i.e. in December 2018, the EPO stopped further decision-making under Rule 28(2) until G3/19 was published in 2021. In this time (July 2017 until December 2018), patents were, e.g. granted to Enza Zaden, covering plants inheriting genes originally detected in model plants which were supposed to improve resistance to plant pathogens (see Figure 10). These granted patents cover all plants derived from further breeding and those inheriting the described genes, regardless of whether they were found in nature, triggered by random mutations or created using targeted technical means (see, for example, EP2455479 claim 1). The EPO did not include disclaimers in these patents. In another case, in October 2018, a disclaimer was added to a patent held by Carlsberg after an opposition was filed. While the barley plants covered by the patent were derived from random mutagenesis and regarded as a patentable invention, the disclaimer stated this patent would only be valid "with the proviso that the barley plant has not exclusively been obtained by means of an essentially biological method." However, this disclaimer had no effect in regard to the barley plants with random mutations claimed by Carlsberg.

In June 2022, a patent was granted for German Company KWS (Kleinwanzlebener Saatzucht). EP3560330 is covering maize with improved digestibility. The patent claims plants derived from random mutations as well as from genetic engineering. In addition it claims the usage of naturally occurring gene variations for screening and selecting the plants within the process of conventional plant breeding. This patent is a precedent: It is the first patent which was granted on a patent application filed after July 2017 and which is of relevance for Rule 28(2). According to the decision G3/19, rule 28(2) had to be applied in this case. Indeed, a disclaimer was introduced (in claim 3), but it only has some limited effect: the patent still covers randomly mutated plants and the usage of genetic variations for the screening and detection of plants within the process of conventional plant breeding. Thus the patent as granted, is not confined to genetic engineering, but is also impacting conventional breeding of the respective plants.

In the most recent patent applications (Table 2), it appears that the industry is now using a specific strategy to escape Rule 28(2). These newer patents no longer refer to processes applied in plant breeding, but simply claim gene variants and all of their usages, e.g. in screening, selection, crossing, genetic engineering (including genome editing) and further breeding. In a pharmaceutical context, patents on genes are granted if they are isolated from their natural setting, such as those from human cells (based on Article 3 of the EU patent directive). Companies in the field of plant breeding now seem to be following a similar strategy:the patents do not claim the gene variants in native plants (such as wild relatives of a domesticated species), but claim its usages in plant breeding. The companies are trying to establish the idea that if patents are granted on the use of gene variants in plant breeding, the exclusions in regard to essentially biological processes are no longer relevant. This strategy could completely undermine the prohibitions in article 53(b) and rule 28(2).

The current legal uncertainty requires political decision-making to draw a clear line between technical inventions and usage of random mutations and gene variants. In 2017, the legal and biological differences between conventional breeding and genetic engineering became confused when the CA/56/17 document was issued and used to interpret Rule 28 (2) (see also page 14). This now needs to be corrected. Otherwise, patents such as those listed in Table 2 and Figure 8 might be granted in future. Even if some of them are rejected or disclaimers are inserted, the prevailing legal uncertainties will delay, hamper or block plant breeding needed for, e.g. adaptation to climate change or resistance to plant pathogens. A crucial step in excluding these patents is an adequate definition of essentially biological processes, which includes all usages of random mutations and spontaneous gene variants. Only if such a definition is introduced, can there be any meaningful restriction to the scope of the patents.

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 53b**: In Article 53b 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):** 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.