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 granted on genes, seeds and food represent one of the biggest risks to global food security and regional food sovereignty. Patents create monopolies: If patents on plants and animals are granted, all other breeders in their geographical scope can be blocked from using it for breeding of new varieties or are getting dependent by license contracts. In many cases, the patents also cover the use of the harvested plants for food production and the food products itself.

Patents on genes can block usage of biological diversity for all kinds of breeding, all plants and all animals. Especially patents on variants of important genes can cause a patent thicket for all medium sized and smaller breeders. The breeder's exemption which, under the plant variety protection system, gives free access and freedom to operate to breeders in Europe, becomes a thing of the past.

If this development is not stopped, this will become the end of plant breeding as we know it: There is no possibility for a traditional breeder to use the existing varieties or native populations for breeding without the risk to infringe a patent. In consequence, many breeders will have to stop breeding or will get dependent from bigger companies by signing license contracts with patent holders.

The consequences are not confined to breeders: 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 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. This development also has consequences for the Global South.

Patents on genes and usage of biological resources needed for breeding are an abuse of patent law. Common goods, stemming from wild populations or bred varieties are turned into a private property of companies. Some of them can be regarded as biopiracy, especially if the genetic resources were accessed without taking into account international treaties on access and benefit sharing.

The ongoing controversy about the European Patent Office:

In June 2017, the European Patent Office (EPO) decided that patents on conventionally bred plants and animals should no longer be granted. However, there are still legal loopholes: The EPO does not obey the profound differences between genetic engineering (patentable) and conventional breeding (not technical, not patentable). In current EPO practice, plants derived from random genetic changes are considered to be patentable inventions.

Several companies are aware of the legal loopholes and they are filing more and more patents on genes and randomly generated as well as natural occurring genetic variations. These patents also get granted and include all plants (and animals) inheriting those genes, no matter if derived from native populations or bred varieties, from crossing and selection, random mutations or genetic engineering.

There are already several examples showing how the legal loopholes have allowed the EPO to grant such patents, e.g. on beer and barley, tomatoes, melons and lettuce including methods of conventional breeding.

The strategy of the big companies:
As shown in the overview of patent applications provided in this report, companies, such as BASF, Bayer-Monsanto, Syngenta or KWS are systematically trying to exploit the legal loopholes: These companies are among those which are systematically using random mutations and screening of plants for interesting genetic variations to claim them as invention. Some of the patent applications as published in 2021 cover dozens, hundreds or even thousands of genetic variations identified in cereals such as soy and maize as well as in vegetable species such as potatoes, spinach, lettuce, cucumber or fruit plant species like tomatoes and melons. The companies seek patent protection for all plants inheriting these genes and variants of genes, derived from any kind of breeding activities.

At the same time, these companies, in their patent applications, use specific wordings by mixing technical elements (genetic engineering) with standard methods of conventional breeding to give the impression of a technical invention.

If such patents are not stopped, there will be huge implications for breeders, farmers and consumers, who are all becoming more and more dependent on big companies that can control access to biological resources needed for further breeding. Therefore, political decisions have to be taken as soon as possible – otherwise the ongoing legal uncertainty will undermine our global food security.

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

Extended summary

The back door for patents on conventionally bred plants and animals wide open

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

However, the decision did not go far enough. Specific reasons for concern: the Administrative Council based its decision on a document prepared by the previous President of the EPO (CA/56/17). The wording of this document does not differentiate between spontaneously occurring gene variants and random mutations on the one hand, and technical interventions generated through genetic engineering (including genome editing) on the other hand. Therefore, in current EPO practice, randomly occurring mutations and plants (and animals) inheriting it, are considered to be patentable inventions no matter which method or technique was used for breeding them.

This was a door opener for an increasing number of patents: Already in 2016, the EPO, for example, granted patents on barley plants, derived from random mutagenesis. Since that companies file more and more patents on genes and randomly generated as well as natural occurring genetic variations. These patents also get granted and include all plants (and animals) inheriting those genes, no matter if derived from native populations or bred varieties, from crossing and selection, random mutations or genetic engineering.

Recent examples for patent applications on biological diversity, blocking plant breeding:

(1) Patent applications filed by Syngenta /ChemChina cover any usage of thousands of genetic variations (called single nucleotid polymorphism, SNPs) from food plants such as soy and maize which occur naturally and for example can enhance the plants 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 gene variants for all breeding purposes and all plants inheriting the genetic variations, as derived from any breeding activities. In the patent, techniques of genetic engineering (including the application of the gene scissors CRISPR/Cas) are mentioned as well as traditional methods for plant breeding, such as screening for the gene variations of interest and further crossing and selection. Claimed as invention are all resulting plants, their seeds and their harvest.

In effect, other breeders are threatened by major legal uncertainties. For example, it will hardly be possible to find out if soy which show improved resistance against Asian soy rust are inheriting some of the around 5000 SNPs listed in the patent application WO2021154632. Therefore, breeders can no longer use the existing plant varieties for further breeding. They even can not make use of the populations of wild relatives of soy for breeding because all usages of the relevant genes are covered by patents. In effect, these patents are likely to become a non-permissive jungle for all other plant breeders.

(2) Another drastic example is breeding of tomatoes with resistance to a virus called Tomato Brown Rugose Fruit Virus (ToBRFV, also called Jordanvirus). In this case, several companies are claiming various genomic regions as identified on the chromosomes of tomatoes. For example, chromosome 11 of the tomato, is targeted by ten patent applications stemming from five companies (such as Bayer/ Seminis, BASF/Nunhems and Rijk Zwaan), claiming similar genomic regions and also genetic combinations of which some are overlapping. All tomato plants inheriting these genetic variations, derived from any breeding activities, are claimed as invention. The genetic variations claimed in the patent do naturally occur and especially are found in wild species of tomatoes.

Conventional breeders which aim to provide tomato varieties with resistance to the virus, in many cases, will not know about the genotype of their plants. To avoid patent infringement cases, they would have to analyse around a dozen patent applications and screen for all genetic variants described therein. They may have to ask for around a dozen of license contracts. In many cases, the breeders will come to the conclusion that they can not breed any of such tomatoes without expensive patent attorneys and comprehensive laboratory analyses.

This results in ‘over-patenting’and is effectively blocking the access to the biological material needed for breeding for the desired virus resistance by traditional methods. Consequently, legal uncertainties and the threat of expensive legal battles are likely to prevent breeders from generating the urgently needed tomato varieties, except a few big companies.

So far, without patents, under the plant variety protection system, all breeders could freely use all existing varieties to produce a new and better plant variety. This driver for innovation will now come to an end with thickets of patent applications on the genome of food plants.

Recently granted patents on biological diversity, blocking plant breeding for climate change adaption:

(1) An recent example to show how the EPO is using the legal loopholes to grant patents on conventionally bred plants, is EP 2440664, which was issued in April 2022 for company BASF/ Nunhems. Claimed are tomato plants with an improved drought tolerance as well as their fruits and seeds. The relevant genetic information for example was detected in wild relative species of tomatoes.

Specific gene variations were selected, the respective plants crossed and further selected, to establish the trait in varieties which can be marketed. The patent covers all plants with the desired characteristics, no matter in derived from conventional breeding or genetic engineering.

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

(2) In April 2022, the EPO anounced to grant Patent EP2961263 for Bejo Zaden. It claims lettuce (Latuca sativa) which inherits genes from a wild relative Latuca species which can improve resistance to downey mildew. The plants are derived from crossing and selection. According to a database from industry (Pinto) this single patent concerns more than 100 conventionally bred varieties. The same database also shows that, in Europe, already more than 800 conventionally bred varieties are impacted by patents and around 120 of them by several patents in parallel.

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 the decision making of the EPO.

As it can be concluded from its Recitals (1, 2, 52, 53) and Art.16, the EU directive is addressing the technical development of genetic engineering. There is a historical reason for it: Before the directive came into force, the EPO had been stopping the grant of patents on genetically engineered plants and animals (T356/93). This decision triggered a lot of pressure by industry which claimed genetically engineered organisms to be their inventions. Therefore, the EU directive can be seen as a reaction to this situation. However, at the same time, the directive does not provide any indication that the EU wanted to allow also for patents on conventionally bred plants and animals.

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

(1) The directive, on the one hand, allows for patents on technical inventions which concern plants and animals. For example, Art. 4 (2), allows for patents "*if the technical feasibility of the invention is not confined to a particular plant or animal variety"*. This addresses the possibility to transfer isolated genes from one organism to another, by the techniques of genetic engineering.

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.

Therefore, in decisions of the Enlarged Board of Appeal (G2/07 and G1/08) it is made 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, the EPO, despite the decisions G2/07 and G1/08, still considers random mutations as technical inventions.

(2) Art. 3 (2) of the EU directive allows for 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 for patents on genes isolated from the human body (see also Art. 5 of the directive). At the same time, plant genes that are in the context of a plant cell, a plant species or a family of plant species (which can be crossed with each other), can not be considered as 'isolated from its natural environment'.

However, the EPO grants patents on all usages of genetic variations as identified in plants and animals as well as on all plants and animals which are derived from breeding activity and are inheriting the genes. The EPO ignores 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.

Conclusions

Patents create monopolies: If patents on plants and animals are granted, all other breeders can be blocked from using it for breeding of new varieties or are getting dependent by license contracts. In many cases, the patents also cover the use of the harvested plants for food production.

As shown in the overview of patent applications provided in this report, several companies actively try to exploit existing legal loopholes to claim conventionally bred plants as their invention. Companies, as well as the EPO, are seeming systematically to obscure the distinction between conventional breeding and genetic engineering. All plants (or animals) with the characteristics described in the patent, are claimed as an invention, no matter if derived from genetic engineering or conventional breeding.

This strategy is a major cause of problems in regard to the scope of patents: patents granted on plants (or animals) derived from technical processes may encompass plants (or animals) sharing the same genetic characteristics obtained from conventional breeding. This means that, even though they are not deemed patentable, plants (or animals) derived from essentially biological methods for breeding may still fall under the scope of a patent.

If this development is not stopped, continued legal uncertainties and ongoing legal challenges will disable the future of any traditional plant breeding. The consequences will also impact the future of food and agriculture as well as the livelihood of many people, including people from regions in the global south. These are risks that could be further intensified and escalated by ongoing climate change.

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

In the face of ongoing food crises fostered by climate change, wars like in the Ukraine, and political instabilities in many regions, we should not allow property claims on biological diversity to, in addition, hamper breeding of our food plants. This would mean to add another major danger to food security and food sovereignty.

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

This ‘freedom to operate’ is also the precondition for the future of
- diversity in the fields,
- Farmers` rights,
- choice for consumers and
- food security as well as food sovereignty.

According to our analysis, there are three crucial areas that need to be changed to make current prohibitions of patents on conventional breeding of plants and animals effective:

1. Definition of “essentially biological processes”
It has to be made clear that the term “essentially biological processes” covers all conventional breeding processes, including random mutagenesis, as well as all individual steps in the process, such as selection and / or propagation.

2. Definition of ‘products’ used or derived from breeding

It has to be made clear that all ‘products’ used in or emanating from ‘essentially biological processes’ are captured by the exclusion from patentability, including all plant/animal parts, cells and genetic information.

3. Limiting the scope of protection

In the context of plant and animal breeding, the EPO must not grant “absolute product protection”, which enables a patent on a plant or animal derived from a technical process to be extended to all conventionally bred plants with the same traits.

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 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 natural 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 controversy about patents on plants

‘Patents on life’ claiming plants and animals as ‘inventions’ first emerged in Europe in the 1980s when companies, such as Monsanto, started to produce genetically engineered plants. Patents on plant and animal varieties are explicitly prohibited in Europe.[1] Nevertheless, the biotech industry, supported by patent attorneys and the European Patent Office (EPO), has succeeded in making patents on seeds a reality. These developments have been driven by vested interests: agrochemical companies, patent attorneys and the EPO all profit from the patent business. Meanwhile, according to official statistics, around 4000 patents on plants and 2000 patents on animals have been granted in Europe, most of which are genetically engineered.

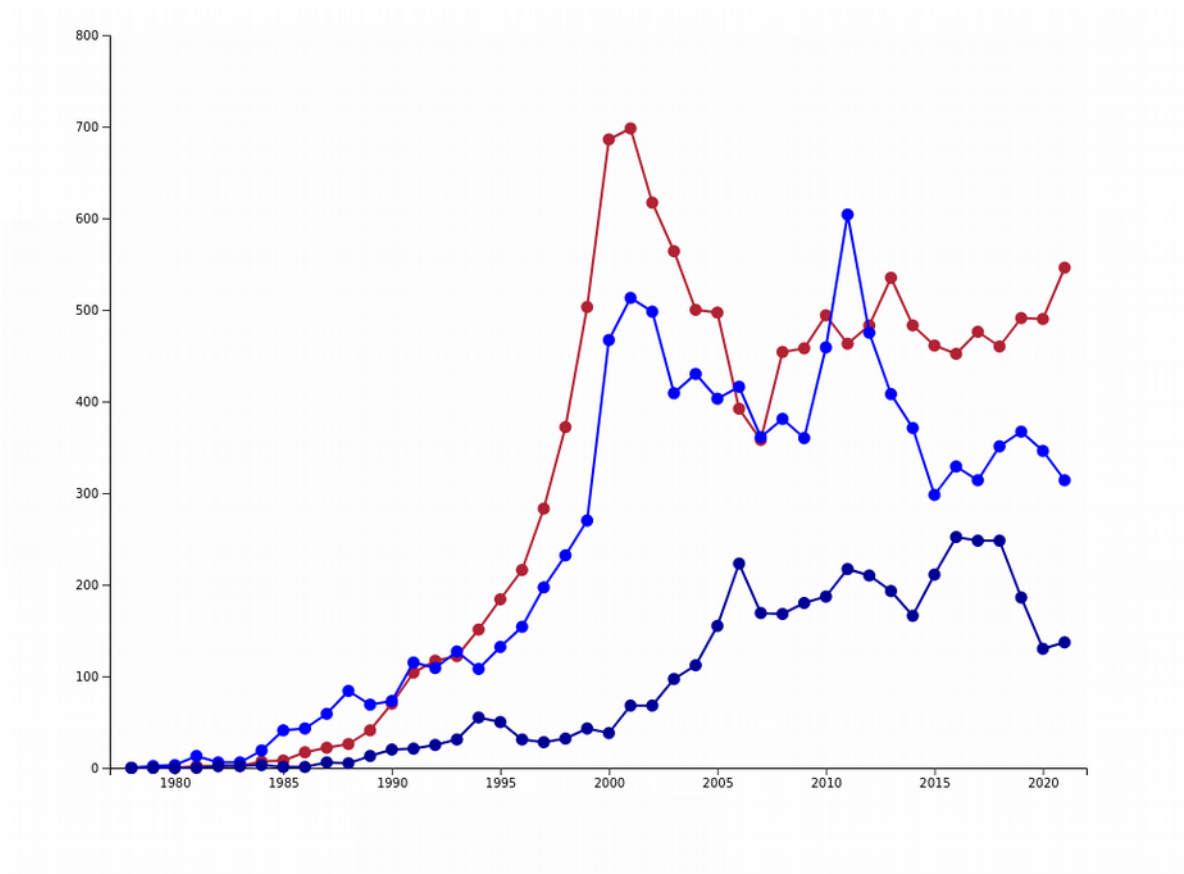


Figure 1: Patents on plants - number of patent applications for all plants under PCT/WIPO (upper /red line) and at the EPO (middle / blue line) as well as patents on plants granted by the EPO (lower line) per year. Research according to official classifications (IPC A01H or C12N15/82). Source: www.kein-patent-auf-leben.de/patentdatenbank/

There is an alarming trend of patents being extended to conventional breeding: within the last ten years, around 100 new patent applications involving conventional plant breeding in Europe were filed each year (via EPO or WIPO). Out of more than 1.500 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 even more than a hundred of plant varieties.[2] Depending on the business strategy of the patent holder, licenses may be needed or access to biological resources may be blocked.

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

The general problem

Patents create monopolies: plants and animals claimed in patents cannot be used by other breeders, gardeners or farmers for further breeding and subsequent sale unless they have permission from the patent holder. Patents also create uncertainties: pending patent applications and ongoing legal challenges can hamper plant breeders in their freedom to operate and prevent the development of new varieties. In many cases, the patents also cover the use of the harvested plants for food production. This is entirely contrary to the current plant variety protection system (PVP), which in principle allows breeders to use the existing varieties needed for further breeding. Moreover, in regard to animal breeding, there are currently no restrictions on farmers using their livestock for further breeding or selling offspring to other breeders in Europe.

Despite the fact that patents on plant varieties are prohibited in Europe, the European patents granted on conventionally bred plants already cover several hundred varieties: as the PINTO database[3], established by European Seed Association (ESA) shows, at the end of 2020, there were 103 granted European patents listed in the database and the number of varieties affected by these patents was more than 850 (see also Table 1). Out of these, 129 varieties (such as in sunflowers, maize and lettuce) are already concerned by several (up to four) patents. Since the input to the database is voluntary, it is likely that in addition several other patents covering conventional breeding are not listed in the database and also not made accessible via license fees.

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

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

Patent	Content	Company	Number of varieties concerned
EP2961263	Lactuca sativa with 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 prevail if patents on plants and animals are not stopped. They already own more than 50 percent of the international seed market through acquisition of breeding companies from all over the world.[4] Moreover, they could shut down free access to biological diversity needed by other breeders if they also own patents on seeds. A similar process is happening in livestock breeding where companies, such as Genus and Hendrix Genetics, have increasing influence on the international market for breeding pigs, poultry and cattle.

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

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

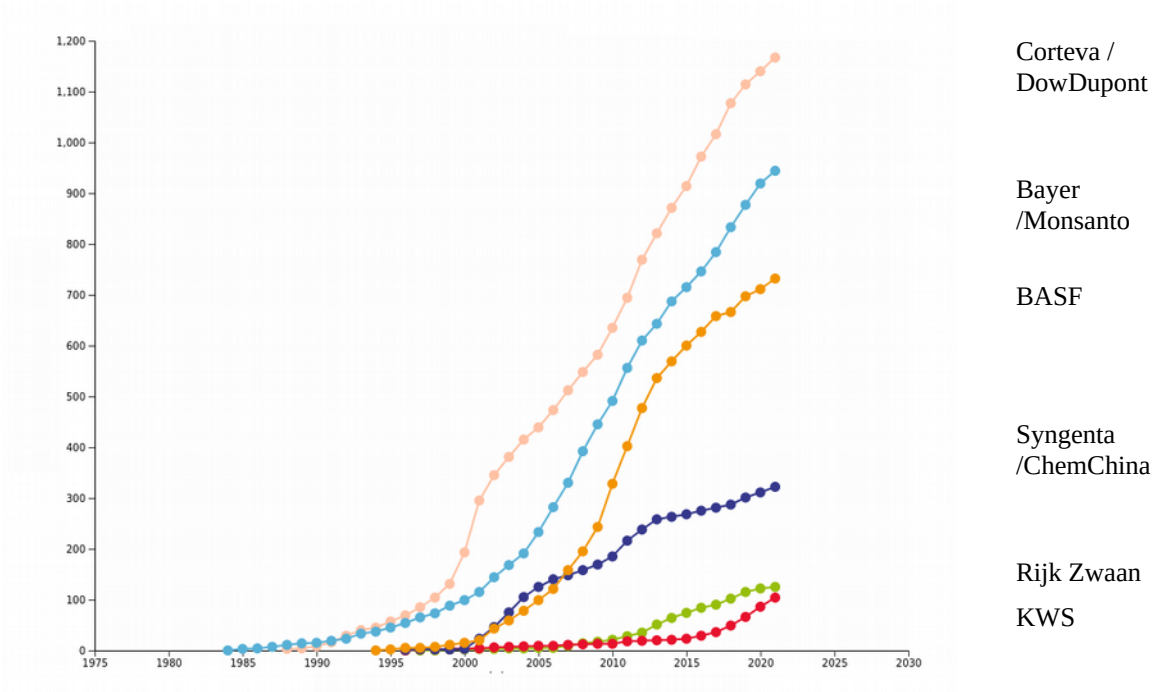


Figure 2: Patents on plants - number of patent applications for all plants under PCT/WIPO categorised by companies, per year, accumulated since 1990. Research according to official classifications (IPC A01H or C12N15/82). Source: www.kein-patent-auf-leben.de/patentdatenbank/

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

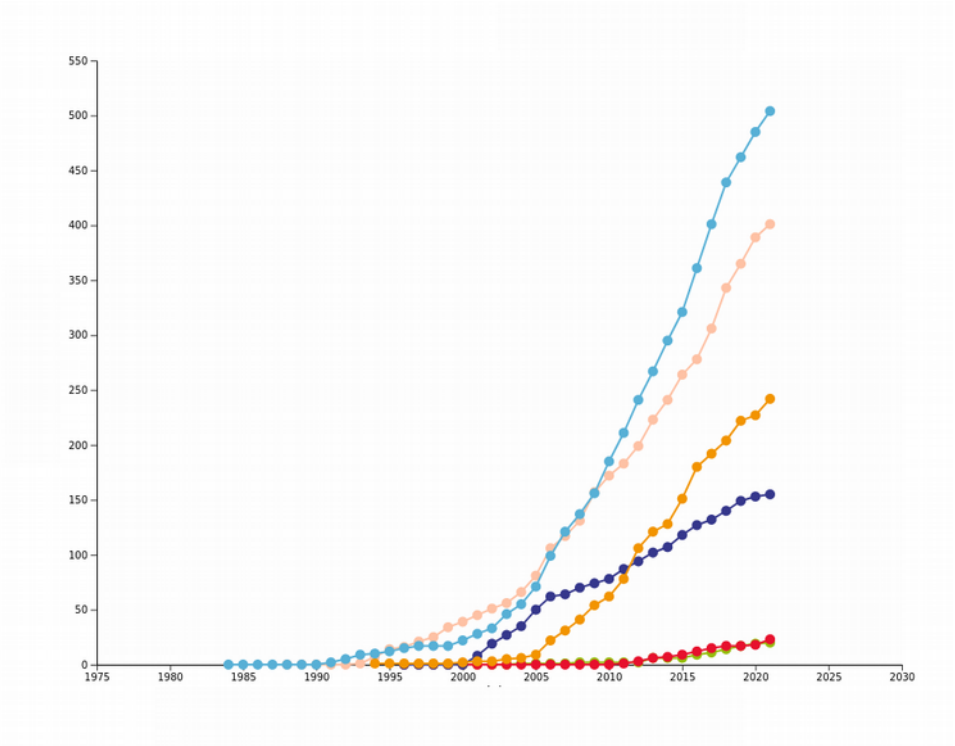


Figure 3: Patents granted on plants by the EPO, categorised by companies, per year, accumulated since 1990. Research according to official classifications (IPC A01H or C12N15/82). Source: www.kein-patent-auf-leben.de/patentdatenbank/

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 regional traditions of production, propagation and exchange of seeds.

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 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.

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

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

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 far reaching consequences. Companies now use specific wording in their patents to mix technical elements (such as usages of CRISPR/ Cas) with standard methods of conventional breeding: (1) Seeds, plants and harvested food derived from random processes 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, to blur the distinction between conventional breeding and genetic engineering.

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

7 European Parliament resolution of 10 May 2012 on the patenting of essential biological processes (2012/2623(RSP)) 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 (2015/2981(RSP)) www.europarl.europa.eu/sides/getDoc.do?type=TA&reference=P8-TA-2015-0473&language=EN&ring=P8-RC-2015-1394

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

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 the gene scissors CRISPR/Cas.

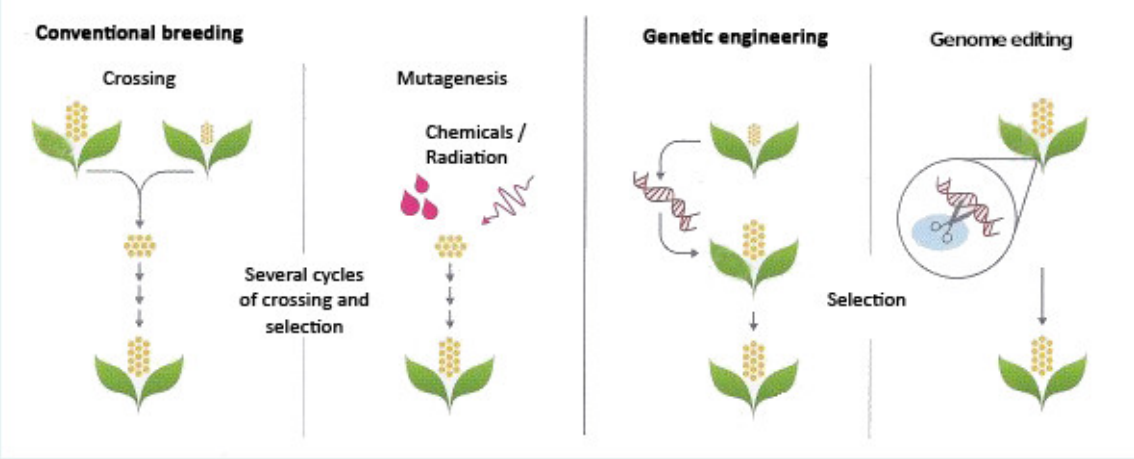


Figure 4: Differences between conventional breeding (including random mutagenesis) versus genetic engineering (including genome editing): conventional breeding always needs several cycles of crossing and selection to achieve to a desired trait, while GE can be used to directly insert new characteristics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

If this distinction is not established in patent law, breeders, gardeners and farmers will still be trapped by patents even if they do not use methods of genetic engineering, e.g. transgenesis or genome editing. Under these conditions, even seeds derived from conventional breeding can no longer be accessed under the conditions of PVP regime, their use will be dependent on contracts with the owner of the patents. The patent holders can hamper, restrict or block access in accordance with their own 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 adopted 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 an 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 as in the years before), around 300 patent applications were published for 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 in those which only describe crossing and selection (due to the decision in 2017, those patents were decreasing in last years), on random mutagenesis (provoking random mutations by physical and chemical means, followed by crossing and selection) which in 2021 were around 10 percent of the patent applications. Also patent applications which claim methods for selection have around 10 percent, while most patent applications are not restricted to specific methods for producing the plants.

Among the applications claiming whole plants (seeds, harvest), we found that a significant number of the patent applications (around 25 % of the patent applications concerning conventional breeding) were issued on plant genes, covering up to thousands of genetic variations. The companies claim all uses of the genetic variations as well as all plants inheriting it, derived from any kind of breeding activities.

In many cases, the patent applications claim genetic variations called ‘single nucleic polymorphisms’ (SNPs). These polymorphisms, which may go along with favorable 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. Very often, the relevant genetic variations are found in native populations which get crossed with the commercial varieties.

The patent applications are not restricted to specific methods to generate the plants. Typical wordings of the claims concern ‘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, simply all plants are claimed which inherit the desired genetic conditions, derived from any kind of breeding

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

activities. In summary, claimed as inventions are the genes (their variations), its usages (such as screening, breeding, genetic engineering) and all resulting plants.

Being aware of this increasing number of patent applications in this category, our research in 2021 focused on this group.

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	WO2021000878 (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 downey 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, plants get exposed to pathogens such as fungal diseases. The plants which show natural resistance to the disease are used for gene analysis and further breeding. In most patents, the so-called ‘technical process’ is just based on the selection of the plants and their use for 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 for the generation of the plants. In many cases, the genes first were detected in wild relative species which may be found in international gene banks. In other patent

applications, the origin of the genes may also can concern plant varieties, previously or currently marketed. In summary, no clear distinction is made concerning the origin of the genetic variations and the methods used to generate the plants.

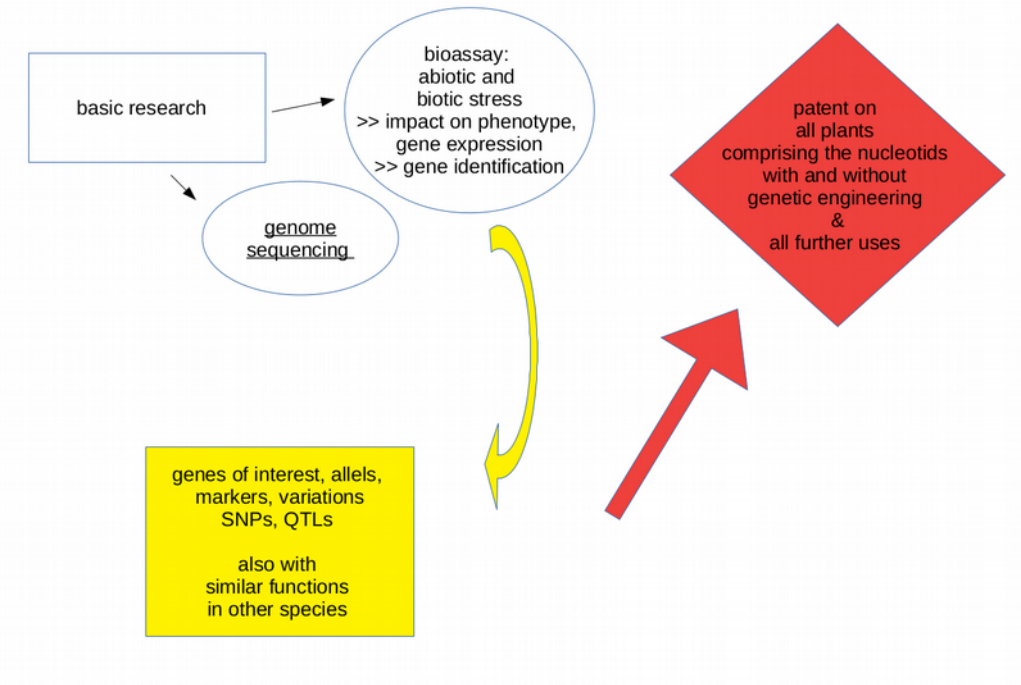


Figure 5: Overview on typical methods used in patent applications to identify genetic variations in plants with favorable biological effects, claimed as 'inventions'.

Case study (1): barley & beer

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

Also the use of the barley for brewing beer is 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 as well as whiskey and vodka. Producing these beverages would be subject to the patent if the 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	Deemed to be 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.

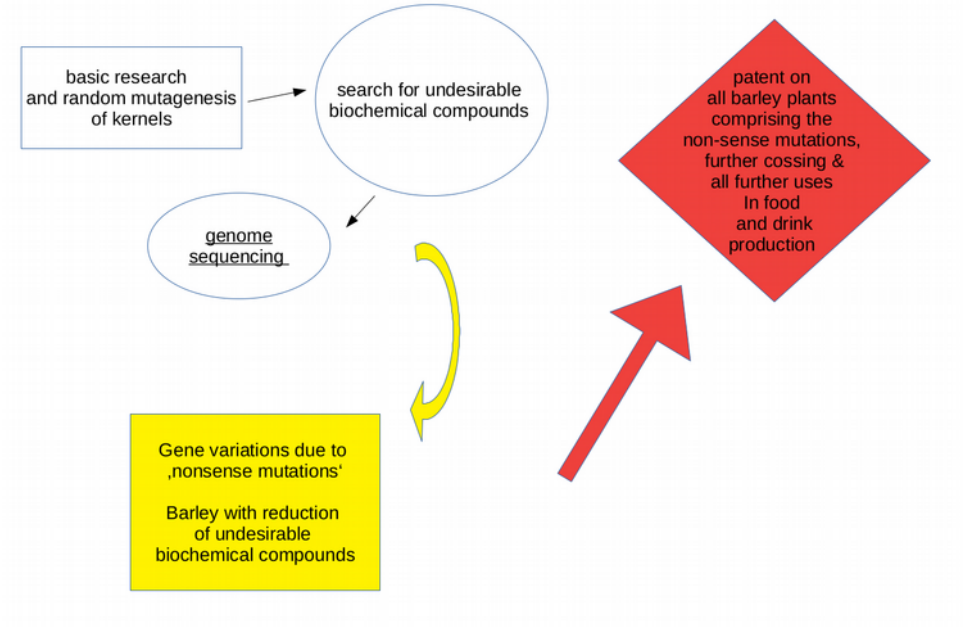


Figure 6: In the case of Carlsberg patents, kernels are exposed to chemical substances known to speed up the numbers of 'random' mutations. The resulting kernels are screened or concentration of specific compounds. Kernels which meet the expectation are additionally analysed in their genome. Barley plants which are inheriting favorable mutations are claimed as 'inventions'.

Case study (2): The Syngenta files

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

It is described that the genetic variations (single nucleotide polymorphisms, SNPs) can be introduced into soy by crossings, marker assisted selection (MAS), genome editing or gene transfer. In the patent around 5.000 relevant genetic variations are listed and claimed as inventions. In the examples it is shown that the genes were detected in wild populations of *glycine tomentella* which were exposed to Asian soy rust (bioassay). The relevant genetic variations then were introduced from the wild populations into domesticated varieties of soy by crossing and selection.

All soy plants which inherit the relevant genetic information are claimed as inventions if they show increased resistance to Asian soy rust (ASR). Also 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, other breeders are threatened by major legal uncertainties. It will hardly be possible to find out if a soy variety which shows improved resistance against Asian soy rust is inheriting some of the SNPs listed in the patent. Therefore, breeders can no longer use the existing plant varieties to create new varieties. They even cannot make use of the wild populations of *glycine tomentella* preserved in various genebanks around the world for breeding because all usages of the relevant genes are covered by patents. In effect, these patents are likely to become a non-permissive jungle for all other plant breeders.

There are several similar patent applications filed by Syngenta /ChemChina in 2021 on thousands of genetic variations (SNPs) from food plants such as soy and maize or also vegetables which occur

naturally and for example can enhance the plants 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)(4906,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)(11219,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)(14093,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,ATGCATAGT,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)(18620,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 favorable variations (allele) is given at a specific position in the genome which may help to increase the plant resistance to Asian soy rust. The overall number of genetic variations claimed is around 5.000 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 and is spreading since then rapidly. Mostly concerned plants are tomato and pepper. It is named because of wrinkly spots (rugose) on fruits. In 2021 five patent applications on tomatoes with resistance to the pathogen were published. As further research showed, already around a dozen international patent applications on ToBRFV resistant tomato plants were filed by companies BASF (Nunhems), Bayer (Seminis), Enza Zaden, Philoseed, Rijk Zwaan and Vilmorin, published from 2018 until 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 are claiming various genomic regions as identified on the chromosomes of tomatoes. For example, chromosome 11 of the tomato is targeted by ten different patent applications stemming from five companies (such as Bayer/ Seminis, BASF/Nunhems and Rijk Zwaan), claiming similar genomic regions and also genetic combinations of which some are overlapping. All tomato plants inheriting these genetic variations, derived from any breeding activities, are claimed as invention.

This case of ‘over-patenting’, is likely to effectively block the access to the biological material needed by all breeders to generate the desired virus resistant plants: Conventional breeders which aim to provide tomato varieties and try to avoid patent infringement cases, would have to analyse around a dozen patent applications and to screen for all genetic variations described therein. They may have to ask for around a dozen of license contracts. In many cases, the breeders will come to the conclusion that they can not breed any of such tomatoes without expensive patent attorneys and comprehensive laboratory analyses. In result, legal uncertainties and the threat of expensive legal battles are likely to prevent breeders from generating the desired tomato varieties, maybe with the exception of very few big companies.

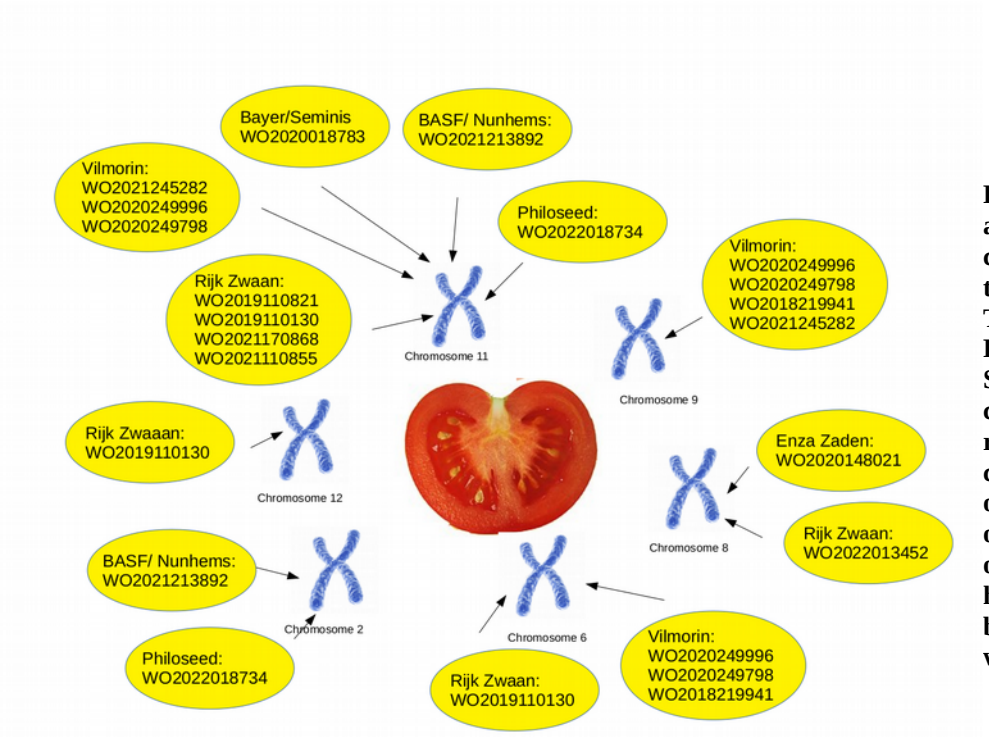


Figure 8: Patent applications from various companies on breeding of tomatoes with resistance to Tomato Brown Rugose Fruit Virus (ToBRFV). Several companies are claiming various genomic regions as identified on the chromosomes of tomatoes, of which some are overlapping. This kind of over-patenting is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

Research into European patents covering conventional breeding and granted in 2021

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

As described in the previous chapters, the genes of interest were detected by performing bioassays or the phenotypical analysis like growth habit. All kind of breeding activities are claimed with these genes, such as 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. But in essence, conventional breeding was the decisive method to generate the plants in all cases.

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 is ignoring the differences between conventional breeding and genetic engineering. Patents are granted on all plants which are inheriting specific genetic variations, which may stem from random mutagenesis and also from other breeding activities. This practice completely undermines and exempts the existing prohibitions in patent law which only allows for technical inventions and excludes patents on conventional (essentially biological) breeding.

Also in the case of the patents as granted, the language of the patents often is confusing, making it difficult to understand to which extent conventional breeding was used for the generation of the plants. In many cases, the genes first were detected in model plant species such as Arabidopsis or wild relative species, also plant varieties, previously or currently marketed, may have be used as a source. In summary, no clear distinction is made concerning the origin of the genetic variations and the method used to generate the plants.

Around a dozen cases of European patents granted were identified in 2021 following all the same strategy of producing and claiming the plants. As the research in patent applications published in 2021 shows, these patents are likely to be just examples for many further patents which will be granted in near future and disable free breeding as guaranteed by breeder's exemption under PVP law.

These patents can block further usages of the genetic information claimed as invention to breed and market new varieties. This is a huge matter of concern especially for conventional breeders, but the patents are likely to also heavily impact applications of New GE such as involving the gene scissors CRISPR/Cas. And also those companies which are active in genetic engineering will be affected: If SNPs get patented, they can no longer be used as a template to direct the cutting of gene scissors like CRISPR/Cas without seeking permissions. It is no longer only the access to the technology which is blocked by patents, but also to the genetic diversity which is needed to apply tools like CRISPR/Cas.

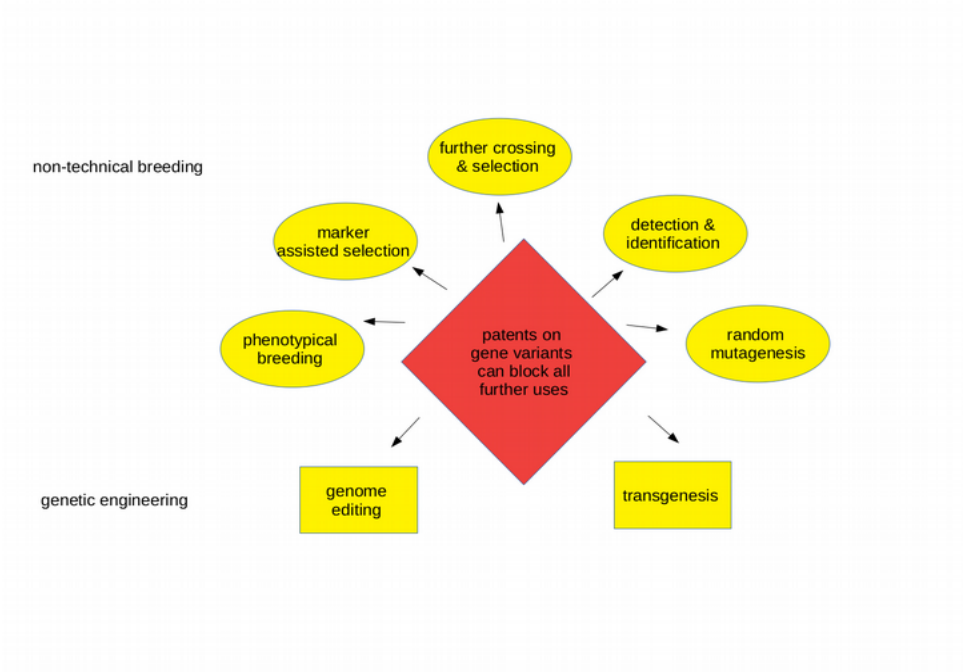


Figure 9: Patents on plant genes can block ~~all~~ further uses of plants and genes, especially for breeding and marketing of new varieties.

Case study (1): One gene turned in seven patents

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.

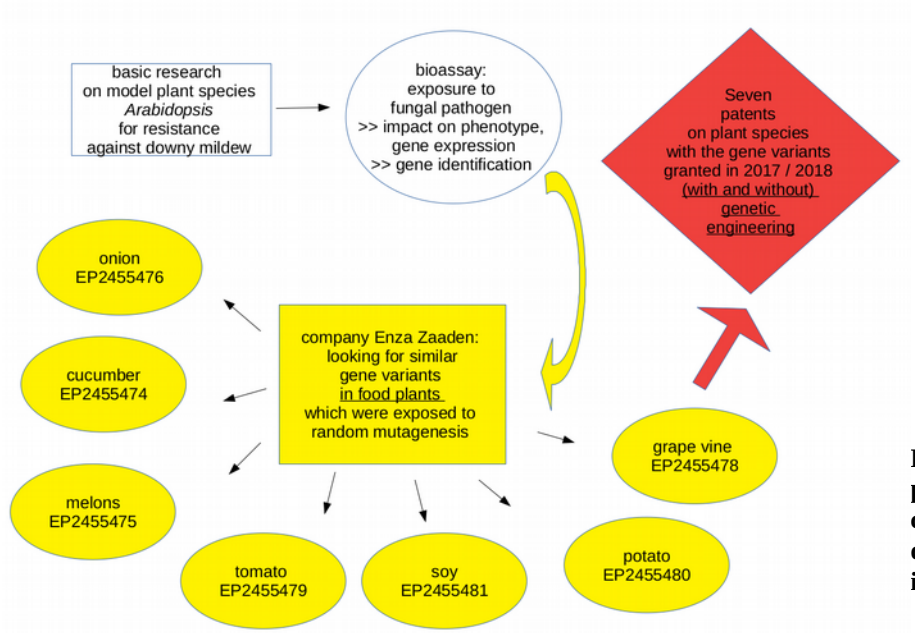


Figure 10: European patents on plants with genes which can confer improved resistance to downy mildew, granted for Enza in 2017 and 2018.

Case study (2): Tomato with drought resistance

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

As it is 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. lycopersicum x S. 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.“

In result, the patent covers all plants with the desired characteristics, no matter in derived from conventional breeding or genetic engineering.

Climate change poses huge challenges, including the question how to adapt our food plants. Before this background, access to biological diversity which is needed for future breeding must not be controlled, hampered or blocked by patents. Such patents put our livelihood at danger.

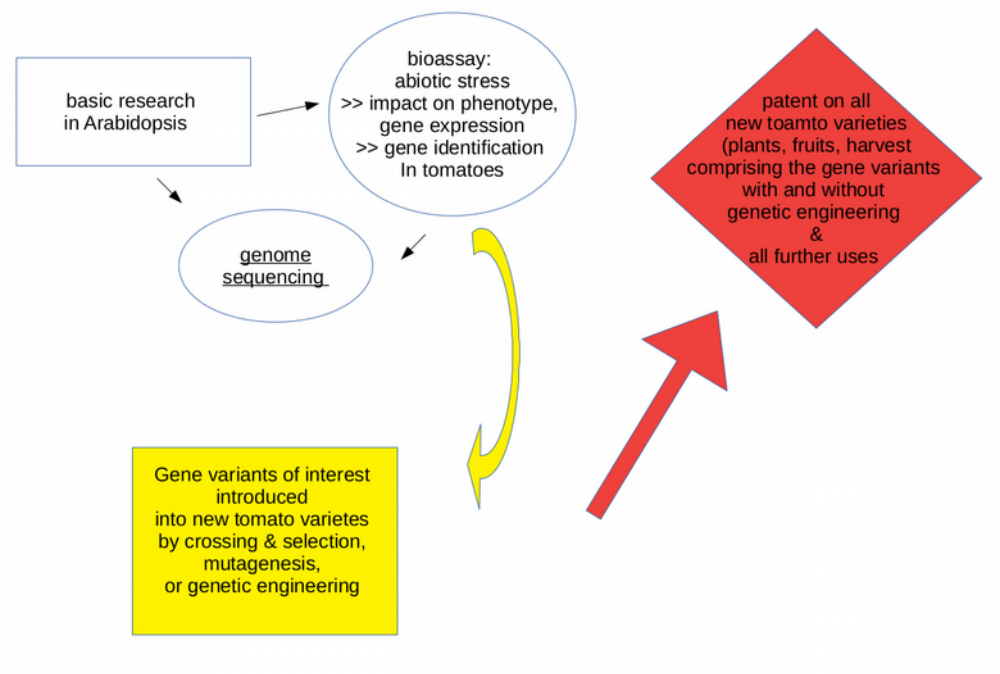


Figure 11: European patent on tomatoes with genes which can confer improved drought tolerance granted for Nunhems in 2021.

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

In April 2022, the EPO anounced to grant Patent EP2961263 for Bejo Zaden. It claims lettuce (*Latuca sativa*) which inherits genes from a wild relative Latuca species which 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.

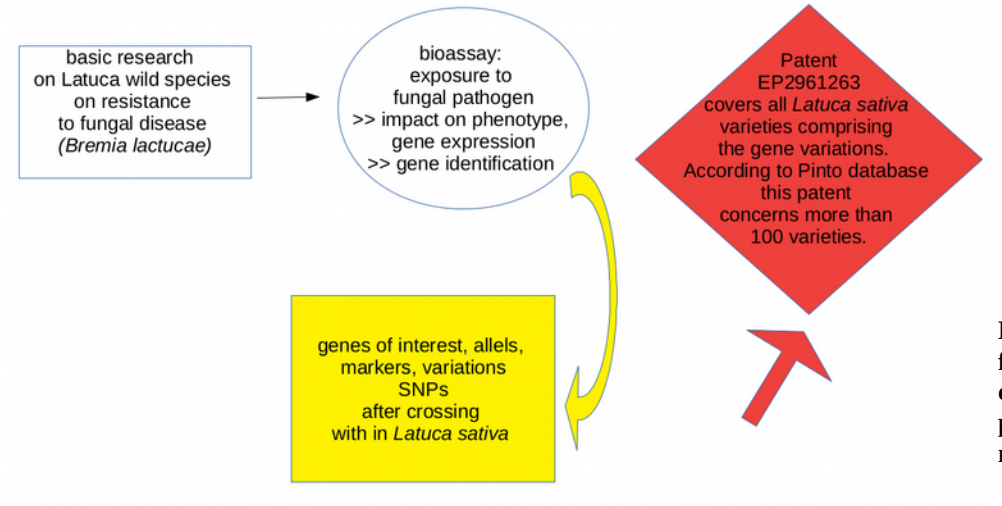


Figure 12: Grant intended for patent on lettuce by company Bejo Zaden. The patent concerns more than 100 varieties.

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 it can be concluded from its Recitals (1, 2, 52, 53) and Art.16, the directive is addressing the technical developments in the context of genetic engineering. There is a historical reason for it: Before the directive came into force, the EPO had been stopping the grant of patents on genetically engineered plants and animals (T356/93). This situation triggered a lot of pressure by industry which claimed genetically engineered organisms to be their inventions. Therefore, the EU directive can be seen as reaction to this situation. However, at the same time, the EU directive does not provide any indication that the EU wanted to allow also for 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 allows for patents only on technical inventions which concern plants and animals. For example, Art. 4 (2), allows for patents if on invention which are "*not confined to a particular plant or animal variety*". This addresses the possibility to transfer isolated genes from one organism to another, by the techniques of genetic engineering. 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 for 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 for patents on genes isolated from the human body (see also Art. 5 of the directive). At the same time, plant genes that are in the context of a plant cell, a plant species or a family of plant species (which can be crossed with each other), can not be considered as 'isolated from its natural environment'.

However, industry claims patents on all usages of genetic variations as identified in plants and animals as well as on all plants and animals which are derived from breeding activity and are inheriting 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"

In 2010, the Enlarged Board of Appeal issued its decisions G2/07 and G1/08 which provided a definition of 'essentially biological processes' for plant and animal breeding (non-patentable) to distinguish them from technical inventions (patentable). It came up with some rather ambiguous wording explaining that patentable inventions are, for example, " (…) *genetic engineering techniques applied to plants which techniques differ profoundly from conventional breeding techniques as they work primarily through the purposeful insertion and/or modification of one or more genes in a plant (cf T 356/93 supra). However, in such cases the claims should not, explicitly or implicitly, include the sexual crossing and selection process."*

In the final statements of the decisions (Headnote 3), it is stated that if there is a "*step of a technical nature, which step by itself introduces a trait into the genome or modifies a trait in the genome of the plant produced, so that the introduction or modification of that trait is not the result of the mixing of the genes of the plants chosen for sexual crossing, then the process is not excluded from patentability under Article 53(b) EPC."*

This ruling is still binding for EPOs decision-making. With the different breeding categories as explained above (Figure 4) in mind, there is no doubt that methods for conventional breeding (crossing and selection with and without mutagenesis) is 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 line with the interpretation of the European Biotech Directive 98/44/EC presented by the European Commission (EC) in November 2016,[13] which concludes that only methods of genetic engineering that directly

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)

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.

However, in preparation for the implementation of Rule 28(2) decision in June 2017, the Administrative Council adopted a document (CA/56/17)[16] which contradicts this definition. The most problematic passage reads: *"Mutagenesis as such is considered to be a technical process which results in a modification of the genome of the plant or animal. This applies to 'traditional' methods like irradiation or chemical mutagenesis, but even more so to molecular methods like Zinc Finger Nucleases, CRISPR, TALEN, ODM (oligonucleotide directed mutagenesis), etc. which require man-made molecules for targeted mutagenesis."* There is no doubt that this document and two other documents published by the Administrative Council (CA/PL 4/17 and CA/PL 4/20) are in conflict with the G2/07 and G1/08 decisions. As shown in 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 the 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 emanating from 'essentially biological processes', would remain patentable. There is no justification for introducing such a specific exemption, which may render the effects of Rule 28(2) ineffective in many cases. This problem is acknowledged in the new Guidelines for Examination. In Chapter G, the guidelines state that no patents on viable cells stemming from plants and animals derived from conventional breeding can be granted if these cells can be used to establish whole plants and animals.[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 that are in the context of a cell, a species or a family of species (which can be crossed with each other), can not be considered as 'isolated from its natural environment' in the meaning of Art. 3 (2) of the EU directive that allows for 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.*"

3. Limiting the scope of protection

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 www.europarl.europa.eu/sides/getDoc.do?type=TA&reference=P8-TA-2015-0473&language=EN&ring=P8-RC-2015-1394

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

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

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

As evidence presented in the 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) sharing the same characteristics obtained by "essentially biological processes". Even though these are not deemed patentable, they may still fall under the scope of a patent.

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

The problem is already recognized by 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 is not a solution yet for European patents which get validated in other countries.

Therefore, we request to develop other solutions, taking into consideration the general difference between claims on the processes and claims on the products. 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 line with the wording of the EU Directive which only allows for technical inventions concerning plants and animals.

Now is the time to act!

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

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

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

Due to legal uncertainties, political controversies or ongoing legal cases, plant breeding might be hampered or even disabled. In particular, smaller breeders might see their business become much less profitable. The future of food and agriculture and our livelihoods could be impacted, and such risks could be intensified and escalated by ongoing climate change.

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

The 'freedom to operate' is the precondition for the future of:
- Diversity in the fields,
- Farmers' rights,
- Choice for consumers and
- Food security and food sovereignty.

According to our analysis, there are three crucial areas that need to be changed to make current prohibitions of patents on conventionally breeding of plant and animals effective:

1. Definition of "essentially biological processes"
It has to be made clear that the term "essentially biological processes" covers all conventional breeding processes, including random mutagenesis as well as all individual steps in the process, such as selection and / or propagation.

2. Definition of 'products' used or derived from breeding
It has to be made clear that all 'products' used in or emanating from 'essentially biological processes' are captured by the exclusion from patentability, including all plant/animal parts, cells and genetic information.

3. Limiting the scope of protection
In the context of plant and animal breeding, the EPO must not grant "absolute product protection" that enables a patent on a plant or animal derived from a technical process to be extended to all conventionally bred plants with the same traits.

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

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

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

Annex:

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 has 38 contracting states, including non-EU countries such as the United Kingdom, Switzerland and Turkey. The Administrative Council is a supervisory body composed of representatives from the 38 contracting states of the European Patent Organisation. The Administrative Council, although it is responsible for overseeing the work of the EPO, has a complete lack of transparency and does not allow the participation of civil society organisations, such as *No Patents on Seeds!*. In contrast, industry is invited as an observer to Administrative Council meetings, with representatives from the lobby groups BusinessEurope[21] and the European Patent Institute (epi)[22] present.

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

As a result, the patent system no longer strikes a balance between the interests of society and the interests of the industry to get patents on technical inventions. Patents are abused to claim biological resources and to turn living beings into patented products.

New problems arising from the EU Unitary Patent

The situation will become even more pressing for several European countries in the next few years, as soon as most of the 27 member states of the EU become part of what is called the Unitary Patent (UP) 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 states (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.

21 www.businesseurope.eu/
22 https://patentepi.org/de/
23 https://www.unified-patent-court.org/about

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]

Are gene patents biopiracy?

Whether the access and use of a genetic resource was unlawful can only be answered by knowing the nature of the access and the donor country. The Nagoya Protocol and the International Treaty on Plant Genetic Resources, among others, play an important role here. The Nagoya Protocol on Access and Benefit-Sharing, was negotiated within the framework of the Convention on Biological Diversity, to regulate the 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. As of today 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 utilization 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. As of today the ITPGRFA has 149 Contracting Parties (including the EU). The Multilateral System of the Treaty facilitates access to the genetic materials that are under the management and control of the Contracting Parties of 64 crops for research, breeding and training for food and agriculture.

1. Access through a genebank 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 into it, 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.

24 https://www.consilium.europa.eu/en/documents-publications/treaties-agreements/agreement/?id=2013001

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 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 programme 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.

<u>Due to the lack of disclosure of origin, infringements are covered up.</u>
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.

Glossary

- Administrative Council: The Administrative Council represents the 38 Contracting States of the European Patent Convention (EPC), comprising all the member states of the European Union together with Albania, the former Yugoslav Republic of Macedonia, Iceland, Liechtenstein, Monaco, Norway, San Marino, Serbia, Switzerland and Turkey. The

Administrative Council is a supervisory body responsible for overseeing the work of the EPO. The Administrative Council nominates the president of the EPO and can decide on the interpretation of the EPC and its so-called Implementing Regulations.

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