



Safeguard the patent-free zone of classical plant breeding in Europe!

Patents granted by the European Patent Office put pressure on politics

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Summary

In 2023, the European Commission published a proposal for the future regulation of plants obtained from new genetic engineering (new genomic techniques, NGTs). This proposal foresees fast-track market access for most of the NGT plants currently being developed.

Concerns were raised that there would be a drastic increase in the numbers of patents on seeds after NGT plants had been introduced into European agriculture. High numbers of patents on seeds could potentially disrupt existing food production systems and plant breeding by blocking or hampering access to biological resources. Therefore, the discussion on the future regulation of NGT plants necessarily includes questions concerning the patentability of seeds.

The European Parliament, the European Commission, EU Member States and experts have made various proposals to facilitate access to biological material needed by all breeders and to stop patents on seeds. In summary, there are at least four key points to be taken (and potentially combined) from the current discussion on changes in patent law regarding plant breeding:

1. Excluding patents on plants obtained from classical breeding (including random mutagenesis);
2. Excluding patents on plants obtained from classical breeding (including random mutagenesis) and certain NGT plants
3. Mitigating the negative effects of patents on plant breeding by introducing a full breeders' exemption into patent law
4. Increasing transparency in regard to patents applied for and granted, including the impact on varieties on the market.

In this report, we provide an overview of patents recently filed and granted in Europe as well as on selected decisions taken by the European Patent Office (EPO). One example is a patent on breeding of a native trait in tomatoes, just based on crossing and selection. The patent (EP3911147) was filed in 2019 and granted in July 2025 for company Enza Zaden. The patent shows how the current European rules and laws can be circumvented: The European Patent Convention (EPC) prohibits patents on plants derived from crossing and selection since 2017. The patent is also highly relevant for the discussion about plants obtained from new genomic techniques (NGTs): The patent as granted is just based on crossing and selection as used in traditional breeding. But naturally occurring genes could also be used and patented for NGT applications. Although using such genes would mean to imitate what is already found in nature, the EPO still would declare it as 'inventive'.

We show that patents on conventionally-bred seeds have a detrimental impact, especially on smaller and medium-sized breeders, which threatens their breeding activities as a whole. Surprisingly, we found that the number of patents being filed and granted on plants obtained from classical breeding is much higher than that for NGT plants. This is worrying since the biological material used and produced with classical breeding methods is needed by all breeders. Therefore, this problem should be prioritized and dealt with as a matter of urgency.

Our findings show that:

- An increasing number of patents are being filed and granted on plants obtained from classical breeding;
- A high number of conventionally-bred varieties are affected by these patents;
- There are historical, technical and legal reasons to exclude patents on classical breeding and the seeds obtained thereof, and only allow patents on the processes of genetic engineering;
- Current EPO practice, however, ignores the fundamental differences between processes such as genetic engineering and classical breeding;

- EPO practice is making the prohibition on the patenting of plant varieties meaningless; the Plant Variety Protection (PVP) law is becoming dysfunctional;
- Consequently, current EPO practice is putting the existence of small- and medium-sized breeders in Europe at risk as well as agrobiodiversity and consumer choice.

We propose that the EU should give top-level priority to clarifying that classical breeding is only subject to PVPs, but not to patents. In this report, we set out a new proposal for the amendment of patent law in accordance with international patent law, in order to overcome some of the current obstacles and to promote short-term solutions. Our proposal follows the logic and the intention of the EU Patent Directive 98/44/EC to define certain technical inventions that are exempt from the prohibitions of Article 53 b) and which are, therefore, patentable rather than listing breeding methods (such as random mutagenesis) that are non-patentable.

We propose adding the following clarification to Rule 27 of the Implementing Regulations of the European Patent Convention (EPC):

*“Inventions which concern plants or animals **or their genetic material shall only be patentable if the genetic material is changed directly and in a targeted way, and to an extent previously not available for breeding, and if the technical feasibility of the invention is not confined to a particular plant or animal variety.**”*

In parallel, this wording should also be added to Article 4 (2) of EU Patent Directive 98/44/EC.

This proposal could help to solve several problems:

- It would safeguard access to the biological material needed by all breeders;
- It only foresees a change in the interpretation of current patent law and would, therefore, only require small changes in the EU patent directive and the Implementing Regulations of the EPC;
- It tackles the root cause of the problem (by preventing patents) and does not simply mitigate negative effects created by granting patents on seeds;
- Patents already granted in the field of classical breeding could no longer be enforced in the European Courts.

No Patents on Seeds! demands the problem with patents on seeds is resolved, regardless of whether and how the current GMO regulations are adapted to NGT plants.

1. Introduction

According to Article 53 b) of the European Patent Convention (EPC), plant and animal varieties as well as conventional breeding are excluded from patentability. It states that: “*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 (...)*”.

In 1998, the EU adopted Directive 98/44/EC on the legal protection of biotechnological inventions (EU patent directive). This directive explicitly allowed patents on technical inventions concerning plants and animals to be granted for the first time in Europe. While the prohibitions outlined in Article 53 b) remained in force, legislators introduced an exemption for genetically engineered plants¹. These exemptions from the prohibitions need to be put into context to clarify their effect.

As shown in our annual reports², the EPO not only grants patents on genetically engineered plants, but also on those derived from classical breeding³. This report gives an overview of recent cases and some statistics. We also exemplify the impact of these patents.

Our research has shown that patents on conventionally-bred plants are in direct conflict with the intention of the legislator. Basically, the legislator never thought that trivial technical steps, such as random mutagenesis or other well-known methods, would be used to turn genetic material into a technical invention.

The EPO has extended the exemptions from the prohibitions in Article 53 b) to the field of conventional breeding. This development is highly relevant for the discussion on NGT plants. If this interpretation is applied in future, patent claims on new genomic techniques can be extended to conventional breeding. In this scenario, there would be a strong increase in the number of plant varieties affected by patents, which would consequently allow patent holders to control future breeding, agriculture and food production, regardless of whether genetic engineering is used or not.

This situation is creating pressure on the political decision makers to take measures to reinforce the correct interpretation of patent law in Europe.

¹ The term genetic engineering only includes techniques that make use of isolated genetic material or biotechnological tools to directly and predictably introduce or modify a plant trait. It can be understood to be equivalent to GMOs that require a specific authorization before entering the market under EU Directive 2001/18/ EC.

² www.no-patents-on-seeds.org/en/background/publications

³ The term classical breeding (or also conventional breeding) includes all techniques and methods used for plant breeding and not considered to be genetic engineering. It also includes GMOs mentioned under EU Directive 2001/18 that do not require a specific authorization before entering the EU market (such as plants obtained by random mutagenesis).

2. Patents recently applied for and granted

In 2024, No Patents on Seeds! conducted comprehensive research into patents on plants and seeds. The researchers used the database, Patentscope⁴, at the WIPO (World Intellectual Property Organisation), as well as Espacenet⁵ at the European Patent Office (EPO) and the Global Patent Index⁶ databases. The aim was to identify patents that had already been granted and filed patent applications relevant to plants with relevance to classical breeding in particular.

All in all, international patent applications (PCT) for plants filed at WIPO were found to account for up to 14.000 applications (from 1980-2024); around 4.000 patents were granted by the EPO. These figures include genetically engineered plants as well as those obtained from conventional breeding (see Figure 1).

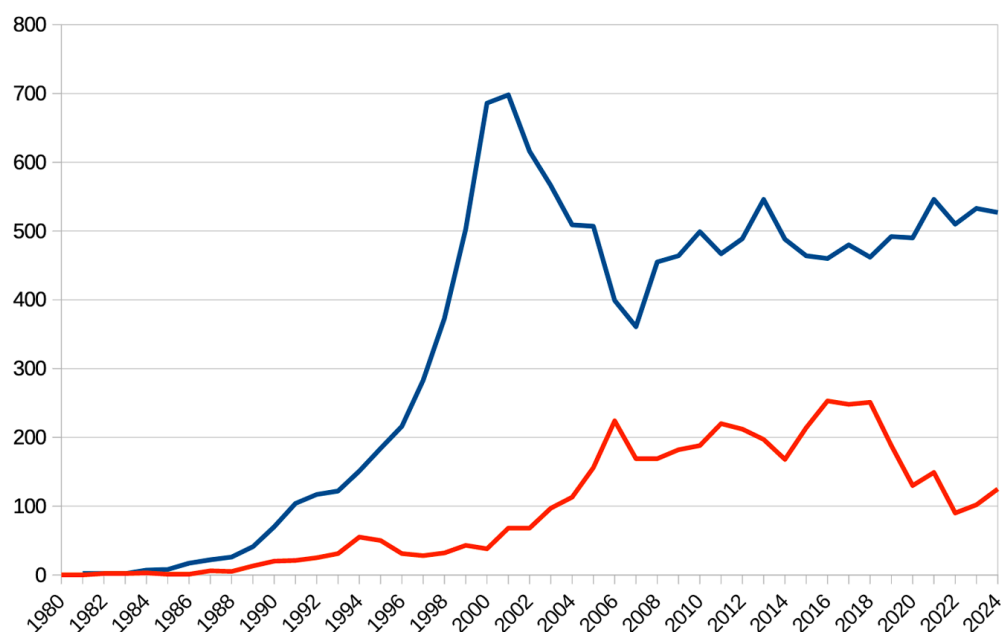


Figure 1: Number of all patent applications filed for plants under PCT/WIPO (upper line) and patents on plants granted by the EPO (lower line) per year. Research according to official classifications (IPC A01H or C12N15/82). Research conducted in Global Patent Index database.

Source: www.kein-patent-auf-leben.de/patentdatenbank

According to the Global Patent Index database, around 500 patent applications for plants were published in 2024. As more detailed research by *No Patents on Seeds!* showed, there were around 90 applications on conventional plant breeding.

In addition, the EPO granted around 40 patents for food plants not obtained from genetic engineering processes, but from classical breeding. Around half of these patents claim plants with improved tolerance or resistance to plant pathogens, such as viruses and fungal diseases⁷. This is extremely worrying, as plant breeding has an important role to play in delivering new varieties with improved tolerance or resistance in the context of pressure from the global spread of pathogens - which can also be accelerated by climate change.

4 www.wipo.int/patentscope/en

5 <https://worldwide.espacenet.com>

6 <https://www.epo.org/en/searching-for-patents/technical/espacenet/gpi>

7 Report *No Patents on Seeds!*, March 2025: *Putting food security at risk: Patents on conventionally bred seeds with resistance to plant pathogens* (<https://www.no-patents-on-seeds.org/en/report-patents>)

2. Patents recently applied for and granted

In many cases, the gene variants that are needed can be found in existing biodiversity. However, patents on plants with improved tolerance or resistance to plant pathogens can significantly hamper or block further breeding, thus putting the interests of the general public as well as agriculture, farmers and breeders at risk.



This threat is bolstered by an alarming case of a patent granted by the EPO in July 2025. The patent EP3911147 of Dutch company Enza Zaden is claiming parts of genes that confer resistance to the Tomato Brown Rugose Fruit Virus (TBRFV) which is a major threat to tomato breeders. The genes were detected in a wild tomato species (*Solanum habrochaites*) which originates from Peru and Ecuador and is known as one of the most important sources of gene variations for tomato breeders. The virus resistant plants were derived from crossing with varieties of tomato plants as marketed in Europe (*Solanum lycopersicum*). Rule 28 (2) of the Implementing Regulations of the European Patent Convention prohibits patents on processes and products derived from crossing and selection. Nevertheless, the patent claims the naturally occurring resistance genes for usage in crossing and selection. Therefore, access to this valuable genetic resources can be hampered or blocked for traditional breeders that do not sign a license contract with Enza Zaden. This case shows how the intention of the legislator to prevent patents on plants and plant material used in classical breeding can be circumvented. Furthermore, it shows that the activities of companies even include biopiracy.

According to our own research, the number of European patents filed and granted that concern classical / conventional breeding from 2009 up until 2024 accounts for around 1500 patent applications and around 340 granted patents.

Further research was conducted in the Global Patent Index database to compare these figures with the numbers of patents being filed and granted on plants obtained from new genetic engineering (new genomic techniques, NGTs). We chose the time period between 2013 and 2024 for this purpose. This is because the first patent applications for the most important NGT tool, i.e. CRISPR/Cas gene scissors, were filed in 2013 (see Figure 2).

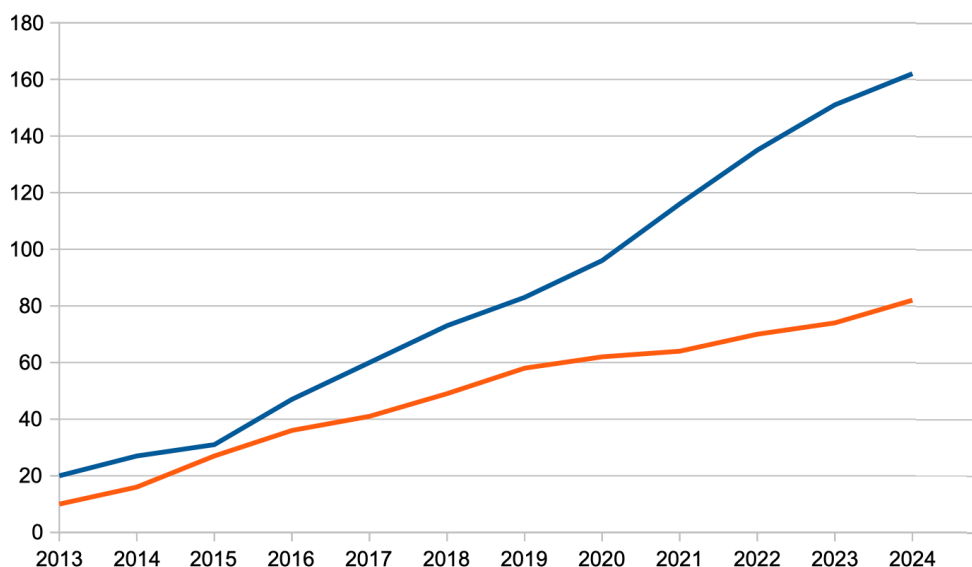


Figure 2: Number of patent applications on NGT plants filed under PCT/WIPO (upper line) and patents on NGT plants granted by the EPO (lower line) accumulated from 2013-2024. Research according to official classifications (IPC A01H or C12N15/82). Research conducted in Global Patent Index database. Source: www.kein-patent-auf-leben.de/patentdatenbank

The number of patents filed and granted for NGT plants is much lower (see Figure 3) in comparison to patents on conventional breeding. This finding is highly relevant for the ongoing debate about seed patents in the EU. So far, this mostly reflects concerns about patents on NGT plants, less attention is being given to patents on classical breeding.

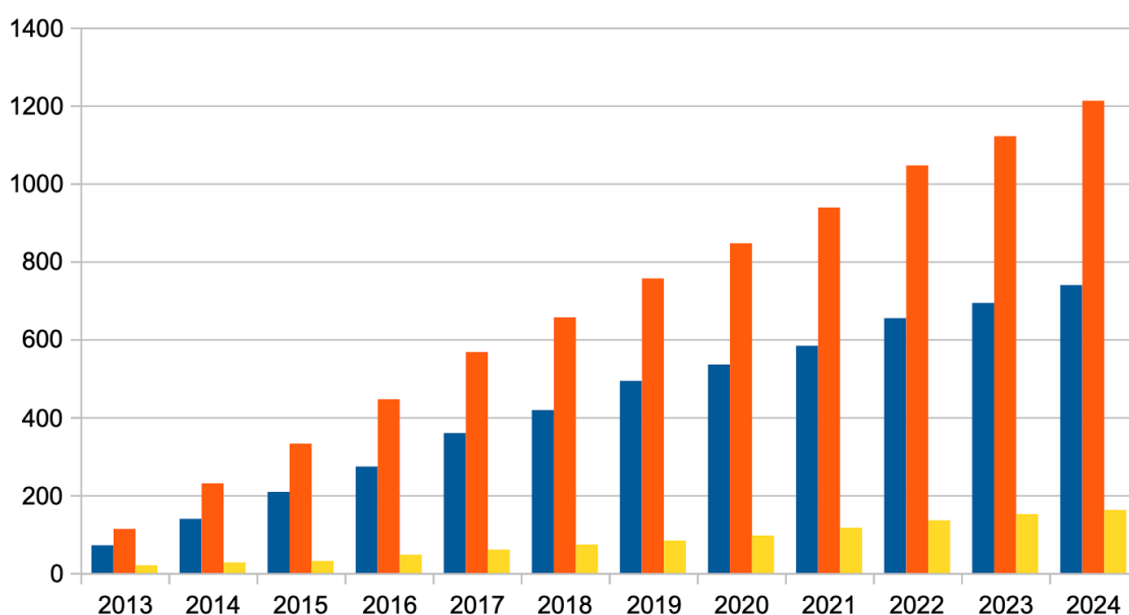


Figure 3: Number of patent applications on plants obtained from classical breeding (first column, blue) or patent applications that concern classical breeding and in addition also genetic engineering (second column, red) in comparison to patents filed on NGT plants (third column, yellow), accumulated from 2013-2024. All applications filed under PCT/WIPO. Research according to official classifications (IPC A01H or C12N15/82). Research conducted in Global Patent Index database. Source: www.kein-patent-auf-leben.de/patentdatenbank/ and further research of *No Patents on Seeds!*.

The high number of patents filed and granted on plants obtained from classical breeding is also mirrored in the PINTO database⁸, which was established by the European Seed Association (ESA). This database lists around 100 European patents on plants obtained from classical breeding, affecting more than 1000 plant varieties belonging to almost 40 plant species.

8 <https://euroseeds.eu/pinto-patent-information-and-transparency-on-line/>

In 2024, the EPO rejected two oppositions filed by *No Patents on Seeds!* against patents on plants and seeds obtained from classical breeding. One opposition was against a patent on lettuce⁹ and another was against a patent on maize¹⁰.



Both patents claim seeds that are relevant for food security: the lettuce supposedly supports food production in higher temperatures due to climate change, while the maize makes it easier to cultivate the plants in Nordic regions. In both cases, the relevant gene variants were detected in existing gene pools. The patents can hamper or block all usage of the relevant biological material for further breeding, even if these are only used for crossing and selection in the classical breeding process. This is despite the fact that Rule 28 (2) of the Implementing Regulations explicitly prohibits such patents.

In their decisions, the examiners refer to decision G3/19 of the Enlarged Board of Appeal. According to this decision, Rule 28 (2) only applies to patent applications filed after 1 July 2017. Because these patents were filed before that day, the EPO was of the opinion that patents could be granted on plants obtained from essentially biological breeding processes. *No Patents on Seeds!* filed appeals in these cases on the basis that patents on plants are not allowed in Europe if these have not been obtained from genetic engineering processes. Therefore, even if Rule 28 (2) is not applied, the patents have to be revoked. As yet, there have been no final decisions in these appeals.



An appeal was filed against the 2023 EPO decision to uphold a patent claiming a bushy melon (EP2814316) granted to BASF (Nunhems). The bushy growth of the plants was, according to the patent description, simply discovered. The only technical step that was added was a well-known method of reducing the number of seeds in the fruits (known as polyploidy). This additional step has no impact on the plants or their bushy phenotype and is thus neither new nor inventive. It was nevertheless deemed sufficient to turn the discovery into a technical invention. The appeal was rejected in 2025.

The case of the bushy melon shows that the EPO accepts trivial technical elements to grant far-reaching patents on plant material. It also shows that the bushy plants clearly fulfill the characteristics of non-patentable plant varieties. This decision will be binding for similar cases in future, even if Rule 28 (2) is applied. Also, the patent EP3911147 (see above) was granted, despite Rule 28 (2) being applied. It claims the use of naturally occurring genetic resources in crossing and selection for providing resistance to the Tomato Brown Rugose Fruit Virus (TBRFV).

All in all, these cases show that the EPO largely ignores the intention of the legislator to exclude patents on plants and plant material used in and obtained from classical breeding. In response, *No Patents on Seeds!* demanded the implementation of political policies to enforce prohibitions under Article 53 b) and thus ensure that only processes of genetic engineering in plants are eligible for patenting.

9 www.no-patents-on-seeds.org/en/news/lettuce-decision

10 www.no-patents-on-seeds.org/en/opposition

4. Some fundamental differences between plant breeding and genetic engineering

Article 53 b) was introduced into the EPC to avoid overlap between PVP law and patent law. It prohibits patents on plant varieties and essentially biological processes for plant breeding. There is one exemption to these prohibitions as far as genetically engineered plants are concerned (see Chapter 7).

As the cases above show, the EPO ignores the fundamental differences between conventional breeding and technical processes of genetic engineering. This allows the prohibitions in Article 53 b) to be circumvented. Table 1¹¹ below sets out some crucial differences in order to distinguish between conventional breeding (including random mutagenesis) and genetic engineering in regard to patent law.

Table 1: Differences between conventional (classical) breeding (including random mutagenesis) and genetic engineering relevant to the interpretation of Article 53 b), EPC.

Criteria	Classical breeding	Genetic engineering
Insertion of traits	Traits can only be established ex-post, from pre-existing genetic diversity (that may also be caused by random mutagenesis) by crossing and selection.	Traits can be predicted (ex-ante) and directly inserted.
Transfer of traits	Traits (genetic information) can only be exchanged between the plants (crossing and selection) or by protoplast fusion.	Traits (genetic conditions) can be isolated and transferred or inserted via technical means.
Species borders	Traits can only be exchanged within species borders (closely related species, breeders' gene-pool).	Traits can be transferred or introduced without being limited by borders between the species.
Genetic diversity	The natural or induced genetic diversity limits the potential selection of desired genetic conditions (traits).	The traits are not limited by pre-existing genetic diversity.
Genetic background	The impact of the genetic background differs from case to case and can be influenced by further crossing and selection.	The impact of the genetic background can be reduced or silenced via technical means (such as additional promoters).

11 First published in: *How CRISPR patents block conventional breeding* (2024, www.no-patents-on-seeds.org/en/publications/CRISPR)

4. Some fundamental differences between plant breeding and genetic engineering

Classical or conventional breeding is always based on genetic material that is embedded in the genetic background of the donor or receiving plants within the same gene pool, regardless of whether this genetic material originates from crossing or random mutations. At no time during the whole process of breeding is genetic material isolated from its natural environment, i.e. the plant genome. The intention of PVP law is to promote this exchange of traits between plants within the breeders' gene pool, by providing access to this biological material via the breeders' exemption. Allowing patents on the characteristics of conventional plant varieties would completely undermine the exemption. This is exactly what the legislator wanted to prevent. The prohibition on the patenting of plant varieties would be meaningless and the PVP law dysfunctional.

In the case of genetically engineered plants, i.e., where genetic material can be technically processed and made available for introduction into the genome of plants, the genetic material cannot be protected under PVP law. Therefore, it is only in this particular instance that plant material is eligible for patent protection. In the case of classical resp. conventional breeding, there is no such plant material and no loophole in intellectual property law.

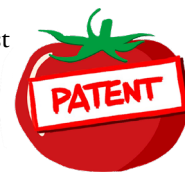
These findings are in accordance with EPO examination guidelines stating:

“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 (see T 356/93). However, in such cases the claims must not, explicitly or implicitly, include the sexual crossing and selection process.”¹²

¹² <https://www.epo.org/en/legal/guidelines-epc>, Part G – Chapter II
5.4.2 Essentially biological processes for the production of plants or animals, Paragraph 4

5. Negative impact on conventional plant breeding

The case of patents granted on tomatoes with resistance to ToBRFV¹³ exemplifies some of the most pressing problems: the Tomato Brown Rugose Fruit Virus (ToBRFV or TBRFV) was first described in 2015 in Jordan and Israel and has been spreading rapidly ever since. It mostly affects tomato and pepper plants and takes its name from the wrinkly spots (rugose) that appear on fruits. In many cases, the relevant genetic variations that confer resistance were detected in wild relatives of domesticated tomatoes (such as *S. pimpinellifolium* or *Solanum habrochaites*, originating from Ecuador/Peru/Chile). There are also reports that existing varieties provide those specific genetic resources.



Two patents on the conventional breeding of tomatoes with resistance (tolerance) to ToBRFV were granted in 2024:

- The patent, EP 3735125, granted to Rijk Zwaan claims breeding processes involving the usage of naturally occurring gene variants (from *S. pimpinellifolium*) for the selection of the plants.¹⁴
- The patent, EP 3629711, granted to Vilmorin claims exclusive rights to tomato plants with tolerance / resistance to ToBRFV. The plants were detected by growing conventionally bred plant varieties (breeding lines) in the region where the virus is prevalent. The respective plants were crossed and selected, and afterwards propagated via selfing. In addition, methods of the detection and cultivation are also claimed as inventions. The patent also mentions the possibility of obtaining the plants from the use of genetic engineering processes, although these are not necessary.

In addition, in 2025, the patent EP3911147 was granted for Dutch company Enza Zaden. It claims parts of genes that confer resistance to ToBRFV that were detected in wild tomatoes. This patent can hamper or block access to these valuable genetic resources for all traditional breeders that do not sign a licence contract with the patent holder.

A patent thicket has already built up around the genetic resources needed to breed plants with resistance to ToBRFV: the first patent applications were filed in 2017. Meanwhile, more than 20 international patent applications filed by ten different companies, e. g. BASF, Bayer, Rijk Zwaan and Syngenta, have been published. The patent applications cover dozens of gene variants. In several cases, the claims of the different companies overlap in some of the targeted genetic regions.¹⁵

In 2025, breeders, market gardeners, development and environmental organisations filed a joint opposition against the Vilmorin patent, EP 3629711, which claims tomatoes with natural resistance to a virus as a 'technical invention'. The list of opponents includes more than 40 breeders and other organisations. Frans Carree from the Dutch organic breeding company DeBolster which is one of the opponents expressed his concerns to the media:

*"If the monopolisation of conventional seeds is not stopped, we and other companies, may no longer be able to afford to carry on with our traditional businesses. This would have major negative consequences for gardeners, farmers and consumers interested in having access to a broad range of food plants."*¹⁶

¹³ https://www.no-patents-on-seeds.org/en/jordan_virus

¹⁴ This patent was filed after 1st July 2017, thus Rule 28 (2) was applied.

¹⁵ See backgrounder *How patents block the breeding of tomatoes resistant to the harmful Tomato Brown Rugose Fruit Virus*, www.no-patents-on-seeds.org/en/report-tomato

¹⁶ Press release May 2025: www.no-patents-on-seeds.org/en/tomato-opposition

5. Negative impact on conventional plant breeding



Picture 1: Handover of opposition against the Vilmorin patent, EP 3629711, at the EPO in The Hague on 27 May 2025 (Photo: Oxfam Novib)

Information is currently being circulated that patent holders are asking for fees ranging from 50.000€ up to 200.000€ for access to breeding material. In addition, at least in some cases, breeders have to pay five percent of the turnover they achieve with their varieties for which the patented material was used. These extremely high costs are just for a license for *one* resistance in *one* species. An increasing number of similar patents are being granted in Europe on other species, e.g. spinach, lettuce, broccoli, barley or maize.

The Pinto database, which was established by the European Seed Association (ESA now Euroseeds), currently lists 100 relevant European patents affecting more than 1000 conventionally-bred varieties from around 40 plant species. Many plant varieties are even impacted by more than one patent.¹⁷ In regard to the case study above on ToBRFV resistant tomatoes, it is interesting to see that Pinto lists two other patent applications (EP4181663 and EP3720272, not yet granted) filed by Rijk Zwaan, each concerning around 30 plant varieties.

The increasing number of patents on conventionally-bred traits creates considerable legal uncertainty and factual barriers for classical breeding:

- Without the consent of the patent holder, the patented processes cannot be used by commercial laboratories to determine whether patent-protected material is present in conventionally-bred varieties or not.
- It is often impossible to determine whether the respective gene variants actually result from patented processes. In some cases, they may stem from crossing and selection, in others from random mutagenesis or, in future, possibly from NGT applications.
- In many cases, several patent applications are filed for the same or similar traits, e.g. ToBRFV resistance, making it difficult in particular for SME companies to determine which patents could actually be infringed, especially if the companies do not have their own patent departments.

¹⁷ <https://euroseeds.eu/pinto-patent-information-and-transparency-on-line/>

This means that in many cases complex scientific, legal and financial questions have to be clarified in advance of the actual breeding process. The associated uncertainties and problems are likely to jeopardize the very substance of small and medium-sized plant breeding. It should not be overlooked that in many cases, varieties listed in Pinto are already covered by several patents. Furthermore, the database remains non-exhaustive and cannot provide full legal certainty.

The factual over-patenting of genetic resources poses a particular threat to the necessary adaptation of existing varieties to pathogens and climate change, and thus to the foundations of food security. Licensing platforms as suggested by the European Commission (see Chapter 6) are unsuitable for solving these problems. It is neither practicable nor financially viable for small and medium-sized breeders to sign licensing agreements with a large number of patent holders, as would be necessary in many cases. In addition, breeders may naturally try to avoid dependencies on larger companies and therefore be deterred from breeding new varieties with patented traits. Whatever the case, the patents can have a deterrent effect on other breeding operations, and thus cause stagnation in plant breeding for important traits such as resistance to pathogens.

6. The discussion about patents on seeds in the EU

In 2023, the EU Commission published a proposal for the future regulation of plants obtained from new genetic engineering (new genomic techniques, NGTs).¹⁸ This new technology uses enzymatic biotechnological mutagens ('gene scissors') to introduce genetic alterations into the plant genome in a predictable way. Currently, CRISPR/Cas is the most relevant tool for producing NGT plants - some of its inventors were even awarded the Nobel Prize. The first applications in plants were published around ten years ago. Meanwhile, many patents have been applied for and granted on the CRISPR/Cas gene scissors, the technical processes and the resulting plants. Concerns were raised that the introduction of NGT plants in European agriculture would drastically increase the number of patents on seeds, thus disrupting existing food production systems and plant breeding by blocking or hampering access to biological resources and promoting seed market concentration.

Many of these patents are worded in such a way as to include the same traits obtained from classical breeding, especially if random mutagenesis is involved. Therefore, with the arrival of NGTs in agriculture, a strong increase in the number of plant varieties affected by patents can be expected. As a result, the patent holders will be able to control future plant breeding, agriculture and food production, regardless of whether genetic engineering is used or not.

Therefore, the discussion on the future regulation of NGT plants is also a starting point for a new discussion on the patentability of seeds. Several proposals have been made to try and ease access to the biological material needed by all breeders and potentially also stop patents on seeds.

The position of the EU Parliament

The European Parliament has proposed banning patents on NGT plants, and also excluding plants obtained from classical methods of breeding such as random mutagenesis from patenting. In addition, the proposals include restricting the scope of the patents in order to facilitate further breeding, even if plants are patented. It was suggested that the EU patent directive 98/44/EC could be changed for these purposes.¹⁹

Doubts were raised about whether such a change in patent law, excluding not only randomly mutated plants but also NGT plants from patentability, would fall within the scope of EU responsibilities. There are concerns that the EPC itself could become an obstacle to these changes that is hard to overcome. Consequently, the legal initiative may have no effect on the practice of the EPO. Further doubts were voiced that safety issues, e.g. requirements for risk assessment, should not be combined with the patent system.

The position of the Commission and the EU Member States

The Commission and the Council of Member States in its majority do not follow the approach of the EU Parliament. They have not proposed any restrictions in patent law, but only to partially improve transparency in order to help breeders contact patent holders to negotiate licenses. No sanctions are foreseen if there is no transparency.

Criticism was raised that this strategy is associated with high costs and far-reaching dependencies. In particular, this may have a deterrent effect on the future breeding operations of SME breeders, as it would not only end their freedom to operate as guaranteed under the PVP system, but also completely endanger their business (see above). Against this backdrop, some EU Member States want to introduce similar changes to patent law as those proposed by the Parliament. In addition, Austria has already changed its national patent law to exclude patents on randomly mutated plants.

¹⁸ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52023PC0411>

¹⁹ https://www.europarl.europa.eu/doceo/document/TA-9-2024-0067_EN.pdf

A proposal made by some experts

To allow freedom to operate for all breeders, some experts and stakeholders proposed introducing a full breeders' exemption into patent law, by changing the wording of the EU patent directive and the provisions of the EU unitary patent system.²⁰ The proposed wording is:

"(...) the protection conferred by a patent on a biological material possessing specific characteristics as a result of the invention shall not extend to

a) biological material possessing the same characteristics that is obtained independently of the patented biological material and from essentially biological processes, or to biological material obtained from such independently obtained material through propagation or multiplication.

*b) the use of that biological material for the purposes of (i) breeding, discovering and developing of a new plant variety for food and agriculture and (ii) the multiplication, offering and placing on the market of that new plant variety, and (iii) using that new plant variety for any purpose in food and agriculture."*²¹

This approach is also supported in a joint statement issued by the German breeders organization (BDP), together with the biggest German farmers organization (DBV) and several civil society organizations. This joint statement also calls for a prohibition of patents on plants obtained from random mutagenesis and also certain NGT plants.²²

The idea behind introducing a full breeders' exemption in patent law originates from the PVP system. According to the PVP law, the breeders' exemption, as a general principle, allows all breeders to freely use other varieties for their own breeding, including the subsequent marketing of the newly bred variety. This allows progress in classical breeding operations to continuously build on the previous work of other breeders. However, the question was raised of why, in a first step, patents on plants and seeds should be allowed while in a second step, the effects of these patents have to be largely mitigated.

The four positions in the current debate

In summary, there are at least four positions that can be identified (and potentially combined) in the current discussion on changes in patent law regarding plant breeding:

1. To exclude patents on plants obtained from classical breeding (including random mutagenesis);
2. To exclude patents on plants obtained from classical breeding (including random mutagenesis) and certain NGT plants
3. To largely mitigate the effects of all patents on seeds by introducing a full breeders' exemption into patent law
4. To increase transparency in regard to granted patents and the affected varieties on the market.

In the following section, we will show how the history and inherent logic of the existing patent system can be used to open the way for an additional solution.

²⁰ www.no-patents-on-seeds.org/en/analysis

²¹ White Paper, Humboldt University:
<https://www.rewi.hu-berlin.de/en/lf/lm/mzg/humboldt-white-paper-on-ngt-patents-27-1-2025.pdf>

²² Position paper in German on the homepage of Bioland:
<https://www.bioland.de/presse/pressemitteilungen-detail/buendnis-aus-konventioneller-und-oekologischer-land-wirtschaftszuechtung-und-kirche-gegen-patente>

7. The historical, technical and legal background of the EU patent directive
 “Legal Protection of Biotechnological Inventions” (98/44/EC)

7. The historical, technical and legal background of the EU patent directive “Legal Protection of Biotechnological Inventions” (98/44/EC)

In 2017, the President of the EPO provided a document²³ in which traditional methods of breeding, e.g. random mutagenesis, were equated with the new genomic techniques (see also tabled overview in the Annex). This document is considered binding for current EPO practice. However, in the light of the historical, legal and technical background of European patent law, the interpretation as given in this document is invalid.

As mentioned, Article 53 b) of the European Patent Convention (EPC) prohibits patents on plant varieties and processes used in conventional breeding. In 1995, this provision in the EPC was interpreted as a general exclusion of plant varieties from patentability (Decision T356/93). However, in 1998, the EU patent Directive ‘Legal Protection of Biotechnological Inventions, 98/44/EC’ was adopted and for the first time in Europe this allowed patents to be granted on genetically engineered plants. The directive 98/44/EC was subsequently integrated into the Implementing Regulations of the EPC. This new legal situation was then confirmed by the G1/98 decision of the Enlarged Board of Appeal of the EPO.

While the prohibitions outlined in Article 53 b) remained in force, legislators introduced an exemption to the prohibition in paragraph (2). Article 4 (1) and (2) of the EU patent directive reads:

“1. The following shall not be patentable:

- (a) Plant and animal varieties;*
- (b) Essentially biological processes for the production of plants or animals.*

2. Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety. (...).”

Rule 27 of the Implementing Regulations of the EPC integrates Art 4.2 of the EU Patent Directive states:

“Biotechnological inventions shall also be patentable if they concern:

- (a) biological material which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature;*
- (b) without prejudice to Rule 28, paragraph 2, plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety;(...).”*

These exemptions from the prohibitions need to be put into historical and technical context to clarify their scope. At the time when the Directive was being discussed and voted on in the EU Parliament, the European Patent Office (EPO) had stopped granting patents on genetically engineered plants and animals in accordance with the T356/93 decision published in 1995. The subsequent adoption of Directive 98/44/EC with its Article 4 (2) was meant to pave the way for technical inventions in the context of genetically engineered plants and animals.

There are several documents (see tabled overview in the Annex) that can be used to investigate the intention behind the introduction of the patent directive 98/44/EC. Besides the text of the directive itself, there is the original proposal made by the EU Commission in 1989 (which was rejected by Parliament in 1995)²⁴ and the text of the second proposal tabled by the Commission in 1995²⁵ which was adopted by the EU with some

²³ https://www.no-patents-on-seeds.org/sites/default/files/news/proposal_admin_council_epo_june_2017.pdf

²⁴ <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:1995:0661:FIN:EN:PDF>

²⁵ <https://cordis.europa.eu/article/id/5653-proposed-directive-on-the-legal-protection-of-biotechnological-inventions>

7. The historical, technical and legal background of the EU patent directive
“Legal Protection of Biotechnological Inventions” (98/44/EC)

changed wording in 1998²⁶. In addition, there are further documents such as decision G1/98²⁷, an EU Parliament resolution in 2012²⁸ and a Commission Notice from 2016²⁹.

All these documents show that (in regard to plants and animals) the historical, legal and technical background of the Directive is closely related to the – at that time - new methods of genetic engineering. To evidence this finding, we compiled the sources and some relevant quotes in a tabled overview (see Annex). Consequently, the exceptions to the prohibition of patents in Article 53 b) have to be interpreted in accordance with the intention of the legislator, i.e. limiting patents to processes of genetic engineering.

Therefore, the exemption from the prohibitions in Article 53 b) cannot be extended to:

- Genetic material that is not isolated, not altered in a targeted way or not made available for the direct and predictable introduction into the genome of plants by technical means;
- Traits or plants that can also be protected under PVP law.

Such material should clearly fall under the prohibitions of Article 53 b) and lead to the rejection of such patent claims.

²⁶ <https://eur-lex.europa.eu/eli/dir/1998/44/oj/eng>

²⁷ <https://www.epo.org/en/boards-of-appeal/decisions/g980001ex1>

²⁸ https://www.europarl.europa.eu/doceo/document/TA-7-2012-0202_EN.html

²⁹ https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:JOC_2016_411_R_0003

8. The demands of **No Patents on Seeds!** and possible solutions

No Patents on Seeds! is demanding that politicians take action to strengthen the correct interpretation of the prohibitions in Article 53 b), EPC. At very least, patents on classical breeding must be stopped, as these patents can hamper or block access to biological material needed by all breeders, regardless of whether traditional methods or genetic engineering are used. This can be achieved in the short-term. In the long-term, all patents on plants and animals should be banned. There are several proposals already on the table. After looking closely at the already existing positions and some of their obstacles and after having numerous discussions with experts, *No Patents on Seeds!* has put forward a new proposal.

New proposal

To clarify the intention of the legislator, the EU Member States should start an initiative in the Administrative Council of the EPO to amend Rule 27 of the EPC. In parallel, further clarification should also be added to Article 4 (2) of EU Patent Directive 98/44/EC.

The clarification would not name specific applications that are non-patentable. It would follow the logic and the intention of the EU Patent Directive 98/44/EC to define certain technical inventions that are exempt from the prohibitions in Article 53 b) and therefore may enjoy patent protection.

This proposal could help to solve several problems:

- It would safeguard access to the biological material needed by all breeders;
- It only foresees a change in the interpretation of current patent law, and would therefore only require small changes in the EU patent directive and the Implementing Regulations of the EPC;
- It tackles the root cause of the problem (by preventing certain patents) and would not simply mitigate negative effects caused by granting seed patents;
- Patents already granted on classical breeding could no longer be enforced in the European Courts.

We propose adding the following clarification to Rule 27 of the Implementing Regulations of the European Patent Convention (EPC):

*“Inventions which concern plants or animals **or their genetic material** shall **only** be patentable **if the genetic material is changed directly and in a targeted way, and to an extent previously not available for breeding, and if the technical feasibility of the invention is not confined to a particular plant or animal variety.**”*

In parallel, this wording should also be added to Article 4 (2) of EU Patent Directive 98/44/EC.

Explanatory notes: the wording takes into account previous decisions of the Enlarged Board of appeal G2/07 and G1/08 which set criteria for processes of plant breeding that are patentable. A key sentence from this decision reads:

“If, however, such a process contains within the steps of sexually crossing and selecting an additional 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.”

Furthermore, technical inventions are defined as involving the use of tools to engineer the genome directly and in a targeted way. ‘Directly’ and ‘in a targeted way’ can be understood as (1) inserting genetic material from outside into the cells and (2) changes at a specific genomic site in the cells. Therefore, the processes used

to achieve these changes are not established in conventional breeding. This means, for example, that plants or plant material obtained from random mutagenesis cannot be regarded as a patentable invention, as random mutagenesis primarily enhances genetic diversity, but does not engineer the genome directly or in a targeted way. Resulting plants and plant material may be new, but they are not inventive. This wording is in line with the 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 (2016/C 411/03), as well as with the European Parliament resolution of 10 May 2012 on the patenting of essentially biological processes (P7_TA(2012)0202) and the Recitals of EU directive 98/44/EC. Therefore, plant or animal breeding material can only be regarded as technical invention if used in or obtained from processes of genetic engineering.

Furthermore, this wording narrows down patentability to those technical inventions that do not simply reproduce something which already exists in nature or is present in existing plant varieties / gene pools. This requirement can be understood as a specific request in regard to novelty and inventiveness.

Finally, this wording would exclude patents on plants obtained from artificial intelligence in combination with classical breeding, or with naturally occurring gene sequences (see, for example, WO 2023250505), which might otherwise be seen as being patentable (and not derived from essentially biological processes).

Other proposals for excluding patents on classical breeding by correcting current interpretation of Article 53 b):

Article 2 (2) of EU patent directive 98/44/EC would be replaced by:

“A process for breeding of plants or animals is essentially biological, if it consists entirely of conventional breeding techniques such as crossing, selection, or the use of randomly or naturally occurring genetic variations.”

Article 4 (1) of EU patent directive 98/44/EC would be replaced by:

“The following shall not be patentable:

(a) plant and animal varieties,

(b) plant material and parts thereof, as well as genetic information contained therein, which have been obtained by plant material and parts thereof, as well as genetic information contained therein, which have been obtained by non-targeted mutagenesis.

(c) essentially biological processes for the production of plants or animals as well as plants or animals exclusively obtained by means of an essentially biological process and the genetic information contained therein.

(d) the use of naturally occurring gene variants for screening and selecting of plant and animal varieties.”

9. Conclusions

No Patents on Seeds! is demanding that the problem with patents on seeds is solved, regardless of how NGT plants are regulated in future. If the problem is not resolved, there will be far-reaching consequences for classical breeders, it will impact innovation in plant breeding and cause seed market concentration. It will also affect food security, agrobiodiversity and, ultimately, the adaptation of agriculture to climate change.

Several proposals have been made in regard to how the EU could actively solve this problem. *No Patents on Seeds!* prefers solutions that tackle the root cause of the problem, i.e. the patentability of seeds. We have therefore suggested a number of amendments and clarifications to the current patent law, which excludes seeds obtained from classical breeding. This would help to avoid costs and bureaucracy from granting patents in the first place and then afterwards mitigating their legal effects.

We are committed to supporting the goal of achieving freedom to operate for plant breeders in Europe and ready to discuss all real solutions. However, we reject the idea of solely increasing transparency in regard to patents granted on plants or facilitating license contracts, as these measures will primarily increase costs and dependencies for many stakeholders, and ultimately only result in disadvantages for the general public while creating non-justifiable profits for the patent holders.

A promising attempt to solve the current problems could be a clarification added to the EU Directive 98/44/EC and / or directly introduced into the Implementing Regulation of the EPC to define certain technical inventions that are exempt from the prohibitions in Article 53 b) and may therefore enjoy patent protection.

Annex

Tabled overview: historical, technical and legal background of the EU Directive 98/44/EC and its divergence from current practice of the EPO.

document	content	comment
Proposal for a Council Directive on the legal protection of biotechnological inventions COM(88) 496 final — SYN 159 (Submitted by the Commission on 20 October 1988) ³⁰	<i>Recital:</i> <i>Whereas biotechnology and genetic engineering are playing an increasingly important role in a broad range of industries and the protection of biotechnological inventions can be considered of fundamental importance for the Community's industrial development;</i>	This recital (not numbered) shows that new developments in the context of biotechnology and genetic engineering were the starting point to consider this new legal framework.
	<i>Recital:</i> <i>Whereas, in the area of agricultural exploitation of new plant characteristics resulting from genetic engineering, guaranteed remunerated access in the form of licenses of right must be provided for as an exception to the general principles of patent law;</i>	This recital (not numbered) shows that the context in which plants were considered as patentable inventions was genetic engineering. No plants obtained from other technologies are mentioned.
	<i>Article 3</i> <i>2. Notwithstanding the provisions of paragraph 1, plants and plant material shall be considered patentable subject matter unless such material is produced by the non-patentable use of a previously known biotechnological process.</i>	The wording of this article indicates that plants produced by already known methods for classical breeding such as random mutagenesis were not seen as patentable inventions.
EPO, decision of the technical board of appeal T 0356/93 (Plant cells) of 21.2.1995 ³¹	<i>40.4 (...) The stated characterising feature of the claimed plant is, in fact, transmitted in a stable manner in the plants and seeds throughout succeeding generations (...). The working examples in the patent in suit relate to the production of transformed plants from known varieties (...). It is shown with tobacco plants that the plants transformed in this way display normal fertility and that the second generation seedlings are homozygous for the resistance gene. Thus, the transformed plants or seeds of the working examples, irrespective of whether they would meet the conditions for the grant of a breeder's right, are plant varieties as they comply with the definition of the concept of „plant varieties“ (...), being distinguishable, uniform and stable in their relevant characteristics. As a matter of fact, these exemplified varieties may be construed as „essentially derived varieties“, being obtained from known varieties by transformation by genetic engineering techniques (...).</i>	The decision concerned transgenic plants which were declared to be non-patentable. Consequently, the EPO stopped granting patents on plants and animals.

30 <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:1995:0661:FIN:EN:PDF>

31 <https://www.epo.org/en/boards-of-appeal/decisions/t930356p1>

document	content	comment
Proposal for a EUROPEAN PARLIAMENT AND COUNCIL DIRECTIVE on the legal protection of biotechnological inventions Brussels, 13.12.1995 COM(95) 661 final 95/0350 (COD) ³²	<i>Recital (1)</i> <i>Whereas biotechnology and genetic engineering are playing an increasingly important role in a broad range of industries and the protection of biotechnological inventions will certainly be of fundamental importance for the Community's industrial development;</i>	This recital (again) shows that new developments in the context of biotechnology and genetic engineering were the starting point to consider this new legal framework.
	<i>Recital (32)</i> <i>Whereas, in the field of exploitation of new plant characteristics resulting from genetic engineering, guaranteed access must, on payment of a fee, be granted in a Member State in the form of a compulsory licence where, in relation to the genus or species concerned, public interest demands the exploitation of the plant variety for which the licence is requested and the plant variety represents significant technical progress;</i>	This recital (again) shows that the context in which plants were considered as patentable inventions was genetic engineering. No plants obtained from other technologies are mentioned.
	<i>Recital (33)</i> <i>Whereas, in the field of the use of new plant characteristics resulting from new plant varieties in genetic engineering, guaranteed access against a fee must be granted in the form of a compulsory licence where public interest demands the exploitation of the invention for which the licence is requested and where the invention represents significant technical progress;</i>	This recital (again) shows that the context in which plants were considered as patentable inventions was genetic engineering. No plants obtained from other technologies are mentioned.
Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions. ³³	<i>Recital (1)</i> <i>Whereas biotechnology and genetic engineering are playing an increasingly important role in a broad range of industries and the protection of biotechnological inventions will certainly be of fundamental importance for the Community's industrial development;</i>	This recital (again) shows that new developments in the context of biotechnology and genetic engineering were the starting point to consider this new legal framework.
	<i>(2)</i> <i>Whereas, in particular in the field of genetic engineering, research and development require a considerable amount of high-risk investment and therefore only adequate legal protection can make them profitable;</i>	This recital (again) shows that new developments in the context of biotechnology and genetic engineering were the starting point to consider this new legal framework.
	<i>(52)</i> <i>Whereas, in the field of exploitation of new plant characteristics resulting from genetic engineering, guaranteed access must, on payment of a fee, be granted in the form of a compulsory licence where, in relation to the genus or species concerned, the plant variety represents significant technical progress of considerable economic interest compared to the invention claimed in the patent;</i>	This recital (again) shows that the context in which plants were considered as patentable inventions was genetic engineering. No plants obtained from other technologies are mentioned.

³² <https://cordis.europa.eu/article/id/5653-proposed-directive-on-the-legal-protection-of-biotechnological-inventions>

³³ <https://eur-lex.europa.eu/eli/dir/1998/44/oj/eng>

document	content	comment
	(53) <i>Whereas, in the field of the use of new plant characteristics resulting from new plant varieties in genetic engineering, guaranteed access must, on payment of a fee, be granted in the form of a compulsory licence where the invention represents significant technical progress of considerable economic interest;</i>	This recital (again) shows that the context in which plants were considered as patentable inventions was genetic engineering. No plants obtained from other technologies are mentioned.
Text of the new Implementing Regulations of the EPC as adopted by the Administrative Council of the EPO decided on 16 June 1999.	<i>Rule 26 (1) For European patent applications and patents concerning biotechnological inventions, the relevant provisions of the Convention shall be applied and interpreted in accordance with the provisions of this Chapter. Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions shall be used as a supplementary means of interpretation.</i>	This Rule of the Implementing Regulations of the EPC underlines the context and the interdependency with the EU Directive 98/44/EC.
EPO decision of the Enlarged Board of Appeal of 20 December 1999, G 1/98 ³⁴	<i>The inventor in the genetic engineering field would not obtain appropriate protection if he were restricted to specific varieties for two reasons: first the development of specific varieties will often not be in his field of activity and, second, he would always be limited to a few varieties even though he had provided the means for inserting the gene into all appropriate plants.</i>	This decision dealt with the patentability of transgenic plants. The decision was taken in notice of the EU Directive 98/44/EC.
P7_TA(2012)0202 European Parliament resolution of 10 May 2012 on the patenting of essential biological processes. ³⁵	<i>H. whereas patents on products derived from conventional breeding or on genetic material necessary for conventional breeding can undermine the exclusion established in Article 4 of Directive 98/44/EC and Article 53(b) of the European Patent Convention;</i> <i>I. whereas, in the field of genetic engineering, patents can be granted but the prohibition of patents on plant and animal varieties has to be safeguarded;</i> <i>4. Calls on the EPO also to exclude from patenting products derived from conventional breeding and all conventional breeding methods, including SMART breeding (precision breeding) and breeding material used for conventional breeding</i>	The resolution indicates that no other methods for breeding than genetic engineering is meant to be subjected to patent law.

34 <https://www.epo.org/en/boards-of-appeal/decisions/g980001ex1>

35 https://www.europarl.europa.eu/doceo/document/TA-7-2012-0202_EN.html

document	content	comment
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 (2016/C 411/03). ³⁶	<i>Secondly, Article 4(1) of the Directive spells out the basic principle of exclusion from patentability of plant and animal varieties, and of essentially biological processes for the production of plants or animals. As an exception to this rule, Article 4(2) states that inventions which concern plants or animals are patentable if the technical feasibility of the invention is not confined to a particular plant variety (i.e. a plant grouping larger than a plant variety). This exception does not nullify the exclusion in paragraph one of this Article. An example of Article 4(2) is the case of a gene which is inserted into the genome of plants and leads to the creation of a new plant grouping characterised by this specific gene (i.e. genetic engineering). By contrast, the crossing of the whole genome of plant varieties corresponding to an essential biological process would be excluded from patentability.</i>	The Commission Notice confirms that there are only limited exemptions from the prohibitions of Article 53 b) that concern plants i.e. derived from genetic engineering.
CA/56/17 Munich, 06.06.2017 Exclusion from patentability under Article 53 b) EPC of plants and animals produced by essentially biological processes – amendment of Rules 27(b) and 28 EPC. ³⁷	<i>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. (...)</i>	In contradiction to the findings above, in this document from June 2017, provided by the President of the EPO, methods of classical breeding are equated to new techniques of targeted intervention in the genome (new genomic techniques).

³⁶ https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:JOC_2016_411_R_0003

³⁷ https://www.no-patents-on-seeds.org/sites/default/files/news/proposal_admin_council_epo_june_2017.pdf