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Patents on conventionally-bred lettuce reveal European dilemma

European Patent Office - Upcoming hearing on pending opposition

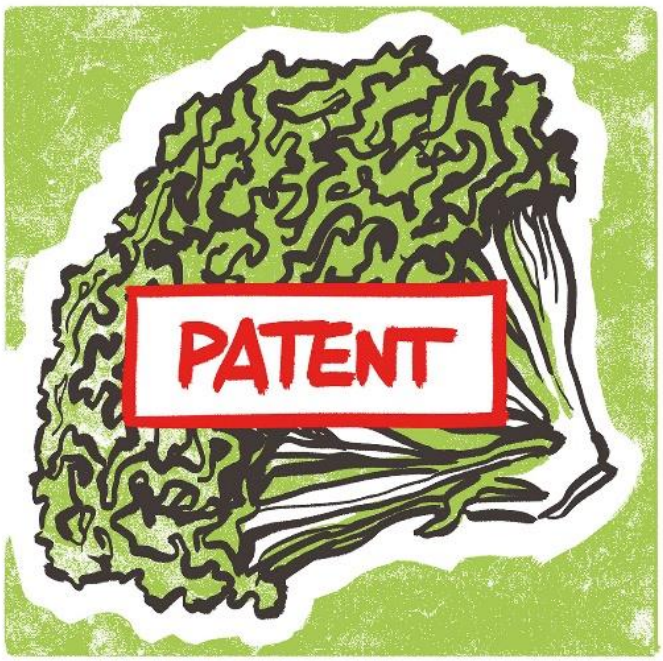


Table of Contents

Summary 2
1. The patent on lettuce 2
2. Further examples 3
3. What is conventional breeding? 4
4. What is a patentable technical invention? 4
6. What is the current legal situation? 5
7. The problem with CRISPR-patents and licencing contracts 5
8. Conclusions and demands 6

Summary

The European Patent Office (EPO) has scheduled a hearing for 7 February on an opposition filed by *No Patents on Seeds!* against a patent granted on conventionally-bred lettuce (EP2966992). This backgrounder has been compiled to provide information on the patent being opposed; it also provides an overview of other patent applications filed for conventionally-bred lettuce. It also discusses options for licencing contracts.

Patents granted by the EPO are already impacting access to more than thousand conventionally-bred varieties, thus undermining the breeders' freedom to operate, which is guaranteed by the European plants variety protection (PVP) law. CRISPR-patents are known as a particular problem in this context, as the scope of these patents frequently extends to conventionally-bred plants.

There is no other solution for this problem than to strengthen the prohibitions in patent law. For example, licencing platforms do not allow independent breeding. Even if, for example, smaller companies were to have access to the patented seeds without payment, they would still need to sign contracts, thus enabling the patent holder to have exclusive control of genetic resources. In addition, there are considerable legal uncertainties, for example in cases where there are several patent holders, or if there are doubts which genetic resources are needed exactly for the development of a new trait. Therefore, the option for licencing contracts is not sufficient to safeguard the right to use all conventionally-bred varieties for the production and marketing of new varieties independently. This right, as guaranteed by PVP law, is one of the main elements driving innovation and food security in Europe.

No Patents on Seeds! demands that the whole spectrum of biological diversity should continue to be available for future conventional breeding. As long as patents on seeds are not completely banned, they must strictly be limited to plants obtained from genetic engineering processes. For this purpose, correct interpretation of European patent laws has to be ensured. Patents on plants must not be granted if their characteristics are based on crossing, selection or random mutagenesis, or on spontaneous genetic changes occurring in nature.

1. The patent on lettuce

The European Patent Office (EPO) has scheduled a hearing for 7 February on an opposition filed by *No Patents on Seeds!* against a patent on conventionally-bred lettuce (EP2966992). The patent was granted for Dutch company Rijk Zwaan in 2018. The 'invention': the seeds are supposedly capable of germinating at higher temperatures. As such, the seeds may be important for future breeding against the backdrop of ongoing climate change. However, patents can be used to hamper or block access to biological diversity needed by all breeders to produce improved, climate resilient varieties.

The patent claims all lettuce seeds, plants, their offspring and any suitable propagating materials with the described characteristics, regardless of whether the plants originated from conventional breeding (such as random mutagenesis) or genetic engineering (including new genomic techniques, NGTs).

Even though in the text of the patent, 'targeted' technical intervention is mentioned, the method used to obtain the desired plants was conventional breeding, starting from a broad range of genetic diversity (derived from random mutations), followed by crossing and selection. Clearly this process cannot be considered genetic engineering, as it does not allow targeted genetic intervention.

The patent is a typical example of how companies are trying to circumvent existing prohibitions by using specific loopholes, i. e. by referring to non-targeted methods of mutagenesis. Evidently, these methods are neither inventive, technical or targeted. Rather, such methods, like all conventional breeding methods, rely on a wide array of genetic diversity or phenotypic traits, which are processed by crossing and selection.

2. Further examples

As shown in the recent *No Patents on Seeds!* report[1], lettuce belongs to the plant species where many patent applications have been filed for conventionally-bred varieties (see Figure 1).

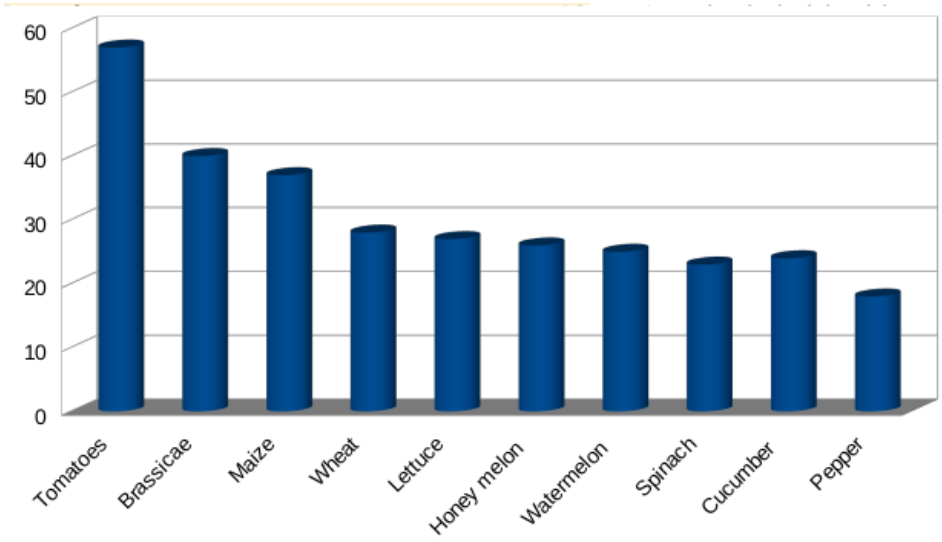


Figure 1: Patent applications filed for conventional plant breeding – the number of patent applications filed between 2012 and 2022, published via the PCT/WIPO (international classifications IPC A01H or C12N15/82) and categorised by plant species. Source: *No Patents on Seeds!* database

Table 1 includes some more recent examples of patent applications filed for conventionally-bred lettuce, which follow a similar strategy to the one that is being opposed. The wording of these patents means that they are likely to escape the prohibitions in patent law for patents on conventionally-bred plants and plant varieties. The reason: the EPO currently interprets conventional breeding as being based on crossing and selection only. It, nevertheless, still allows patents on random mutations to be granted.

Table 1: Recent patent applications filed for lettuce plants obtained from new genomic techniques (NGTs) and from conventional breeding, often re-inventing naturally occurring gene variants

Number Company	Content
WO2023020938 BASF/Nunhems	The patent claims *Lactuca* plants with delayed bolting (start of flowering) to increase their size at harvest. The claimed gene variants may result from either random mutations or NGTs.
WO2023051902 Bejo Zaden	The patent claims *Lactuca* plants that are resistant to a fungal pathogen (downy mildew or *Bremia lactucae*). The claimed gene variants were found in existing plant material and, according to the claims, may be 're-invented' using either random mutagenesis or NGTs.
WO2024002949 Enza Zaden	The patent claims *Lactuca* plants that are resistant to a fungal pathogen (Fusarium wilt or *F. oxysporum)*. The claimed gene variants were found in existing plant material and, according to the claims, may be 're-invented' using either random mutagenesis or NGTs.
WO2023232265 WO2023117154 ENZA Zaden	The patents claim *Lactuca* plants that are resistant to a fungal pathogen (downy mildew or oomycetes). The claimed gene variants were found in existing plant material and, according to the claims, may be 're-invented' using NGTs (such as cisgenesis).

Some of the Dutch companies, including Nunhems /BASF, are amongst the top companies leading the conventional lettuce breeding sector. Therefore, it is not surprising that they have filed the above-described

[1] *No Patents on Seeds!* (2023) The future of plant breeding is under threat in Europe. Current interpretation of patent law is insufficient to stop patents on conventional breeding https://www.no-patents-on-seeds.org/en/report2023

patent applications, partially in response to the ongoing patent race with competing larger corporations. However, it is doubtful whether smaller companies will play a significant role in this 'game of patents' in the longer term.

3. What is conventional breeding?

Conventional breeding has to be understood as methods of producing plants and animals based on crossing and selection, without using technologies to bypass natural biological mechanisms. Essentially, conventional breeding is always based on a wide range of genetic and biological diversity found in natural populations, including in previously bred plant and animal varieties or breeds. Genetic diversity can, for example, be increased if plants are exposed to different types of (natural) radiation or chemicals to amplify the rate of random mutations. Not all of these mutations are beneficial. Therefore, conventionally-bred varieties are the result of subsequent crossing and selection of particular plants that are chosen from a whole range of biodiversity. This process is time-consuming and requires breeders to make careful choices.

The processes involved in random mutagenesis have been used in plant breeding for many decades and are still widely applied. Experts estimate that there are currently thousands of varieties based on random mutagenesis being grown. Until now, breeders could freely use all these varieties to produce new generations of plants and varieties based on the exemptions in PVP law. However, patents like the one granted on lettuce, can severely hamper or block access to these plants for other breeders. There may as well be an accumulation of patents for many varieties, which will increase with every further step of crossing. This will lead to major legal uncertainty if, for example, several patent holders are involved, or where it is not clear which specific genetic resources are needed for the development of a new trait. Thus, these patents are a serious threat to small and medium size breeders and, more generally, to innovation and diversity in plant breeding.

4. What is a patentable technical invention?

Genetic engineering on the other hand uses direct technical and targeted intervention to establish new traits. With new genetic engineering, for example, genes can be knocked out or additional gene sequences can be inserted in a targeted way. This is a fundamental difference between new genetic engineering and 'essentially biological processes' of breeding.

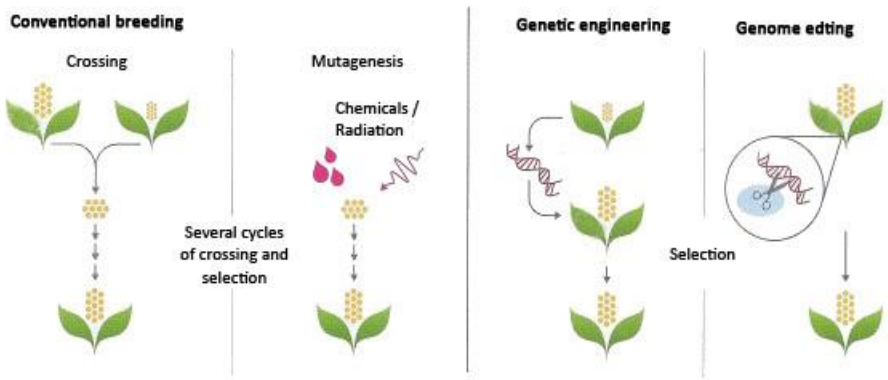


Figure 2: Differences between conventional breeding (including random mutagenesis) and genetic engineering (including genome editing): conventional breeding needs several cycles of crossing and selection, while GE can be used to directly insert new characteristics into a plant.[2]

[2] *No Patents on Seeds!* (2022) 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. *No Patents on Seeds!* https://www.no-patents-on-seeds.org/en/report2022

6. What is the current legal situation?

The European Patent Convention (EPC) is the legally binding law for the EPO and its 39 contracting states. According to Article 53 (b) of the EPC, patents on plant varieties and non-technical ('essentially biological') methods for plant breeding are prohibited. One reason for these prohibitions is the plant variety protection law (PVP), which guarantees access to all varieties on the market for further breeding of improved varieties. Patent law, on the other hand, would restrict access. Therefore, overlap of the two legal systems have to be avoided in order to not hamper innovation in plant breeding.

However, in 1998 the EU adopted Directive 98/44 on the legal protection of biotechnological inventions (EU patent directive). This directive allows patents on technical inventions in plant breeding. As a result, thousands of patents on transgenic plants and animals have already been granted in Europe. However, the law only permits patents on genetically engineered plants: as for example the title of the Directive 98/44 (Legal Protection of Biotechnological Inventions) and the wording of Recitals 52 and 53 of the Directive show, it was not the intention of the legislator to allow the patentability of products obtained from essentially biological processes.

It must, therefore, be concluded, that all conventional breeding processes and all products (plant varieties, plants, animals, their characteristics, their genetic components, seeds, breeding material, gene sequences) are still excluded from patentability under Directive 98/44 as well as under the EPC.[3]

7. The problem with CRISPR-patents and licencing contracts

Companies such as Bayer and Monsanto originally introduced patenting as a strategy to turn their transgenic seeds into lucrative business models. Plants obtained by new genomic techniques (NGT) are now routinely patented as well. Large international corporations, such as Corteva (formerly DowDupont) and Bayer, are leading the way in this respect. Medium-sized European breeders who want to work with new genetic engineering technologies often have to sign contracts with the large corporations, and thus become dependent.

However, these patents also create problems for conventional breeders, as their scope is not limited to genetically engineered plants. In many cases, the strategy of the patent applicant is similar to the one exposed in the lettuce patent: all plants with the desired characteristics are claimed, regardless of whether they are derived from technical inventions or random processes. This is the clear intention of companies seeking to control access to biodiversity, even if no genetic engineering is used.

The EPO has already granted several hundred patents on conventionally-bred plants. In response to these developments, the EU member states, backed by the EU Commission, achieved a huge majority in 2017 in the Administrative Council of the EPC to correct the interpretation of the European patent law, and to exclude patents on conventionally-bred plants and animals. Nevertheless, the EPO is still granting patents on plants inheriting random mutations. Meanwhile, the patents granted by the EPO are concerning more than 1000 conventionally-bred varieties. Several varieties are already affected by several patents simultaneously. The Pinto database[4] lists seven patents for lettuce - covering 236 varieties (see Table 2), with one variety targeted by three patents and 26 varieties by two patents.

These patents are causing major legal uncertainty for many conventional breeders as they may involve several patent holders. It is unclear which of the patents have actually been granted, and it is unclear which specific genetic resources are needed for the development of a new trait. In any case, these patented varieties can only be accessed via licencing contracts, thus creating new dependencies, strengthening the patent holders, controlling and potentially restricting access to biodiversity and weakening the future of plant breeding in Europe.

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3 Correct legal interpretation of Article 53(b), EPC, within the context of the EU patent directive 98/44, Legal analysis provided by *No Patents on Seeds!* https://www.no-patents-on-seeds.org/sites/default/files/news/Interpretation%20Art%2053%20(b)%20_NPoS_0.pdf

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

Table 2: Overview of European patents claiming European lettuce varieties obtained from conventional breeding (Source: www.euroseeds.eu/pinto-patent-information-and-transparency-on-line/)

Title	Patent number	Company	Number of varieties concerned
Lettuce resistant to *Bremia lactucae* (downy mildew)	EP2961263	Bejo Zaden	121
Plant resistant to a pathogen	EP2451269	Syngenta	56
Aphid resistance in composites	EP0921720	Rijk Zwaan	38
Screening method for selecting plants that show reduced wound-induced surface discolouration, and plant and plant parts thus obtained	EP1973396	Rijk Zwaan	38
Method of identifying plant material with reduced discolouration	EP2173157	Rijk Zwaan	7
Method of obtaining a plant with lasting resistance to a pathogen	EP1179089	Enza Zaden	4
Multi-leaf lettuce	EP0942643	Rijk Zwaan	1

8. Conclusions and demands

The independence of traditional breeders in Europe must be maintained. The necessary access to biological diversity must not be controlled, hindered or blocked by patents. As a result, patents on processes based on crossing, selection, the use of natural genetic variations or random mutagenesis must be prohibited, as must the extension of claims in genetic engineering patents to conventionally-bred plants and animals. There is no other solution than to strengthen prohibitions in patent law. As already mentioned, licencing platforms do not allow the kind of independent breeding guaranteed under PVP law. Even if, for example, smaller companies are able to gain access without payment, they still need to sign and fulfill contracts that allow the patent holder to exert exclusive control over the usage of biological resources. The right of breeders guaranteed under PVP law to use all conventionally-bred varieties to produce improved and new varieties must be maintained. It is the only way to safeguard legal certainty for all conventional breeders – and it is only under these conditions that they can continue to be important drivers of innovation and food security.

Austria is leading the way

The legislator in Austria has already successfully amended the national patent law, and thus limited patents to genetically engineered seeds. According to the Austrian Patent Act, patents are not permitted if they are "*based on natural phenomena such as crossing, selection, non-targeted mutagenesis or random genetic modifications occurring in nature.*"[5] For these regulations to become effective at the European level, the EU in particular now has to clarify that only genetically engineered plants can be patented, but not conventionally-bred plants and animals (including random mutagenesis). Similar to Austria, the EU should prevent patents on genetic engineering from affecting conventional breeding. It is not necessary to change the laws for this purpose – it is simply necessary to correct the interpretation of the existing legal prohibitions. A majority of three-quarters of the vote in the Administrative Council of the EPO would be sufficient. The EU could already bring about 27 of the 30 votes needed for a majority.

There is no short-term solution to patents on NGT plants

Some stakeholders are currently creating the impression that the EU could ban patents on genetically engineered seeds in order to increase the acceptance of genetic engineering in agriculture. For example, it is suggested that genetically engineered plants could be exempt from patent protection if they are no longer regulated. This is wrong. GMO regulation has nothing to do with patent law. If patents on genetically engineered plants were actually banned, all 39 contracting states of the European Patent Office (EPO) would

[5] https://www.parlament.gv.at/gegenstand/XXVII/ME/229?selectedStage=100

have to agree. Unanimity would be required to amend the existing laws. The industry, patent attorneys and several EPO contracting states are blocking this necessary move. Therefore, contrary to the situation with conventional breeding, for this purpose, licencing platforms may be considered to be the only realistic option.

Corporations also want to use patents to control conventional breeding

An initiative to ban conventional breeding would be extremely serious: if there is no clear and legally secure interpretation of the prohibitions, corporations, such as Bayer and Corteva, BASF and Syngenta, will soon be able to control all seeds – produced with or without genetic engineering.

The question is not whether NGT plants will be patented – under current legislation this is unavoidable. Whoever cultivates NGT plants will reap patents. The crucial question is whether it is possible to prevent these patents from also affecting conventional breeding. This would have a devasting effect on food security in Europe.