



## Patents on CRISPR/Cas are threatening traditional breeding

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[www.no-patents-on-seeds.org/en](http://www.no-patents-on-seeds.org/en)

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## Summary

In June 2021, the EPO finally granted a patent (EP 2373154) on barley and declared the plants to be a patented invention. The barley covered by the Carlsberg patent is derived from conventional breeding methods and not genetically engineered. According to European patent law, only technical processes, such as genetic engineering, can be patented. The EPO, however, appears to be ignoring these legal provisions: according to a document written by the President of the EPO, random mutations are equivalent to genetic engineering processes. This same interpretation was applied in the case of a barley patent.

In many patent applications, no differentiation is made between genetic engineering and conventional breeding. Instead, all plants with specific genetic characteristics are claimed as 'inventions', irrespective of how they were generated. The CRISPR/Cas techniques, in particular, are frequently used to imitate results originally derived from conventional breeding. If such patents are granted, they cover all the plants (or animals) with the described characteristics (this is called 'absolute product protection' in patent law). Thus, despite many breeders wanting to avoid genetic engineering, this is increasingly under threat, especially from patents on CRISPR/Cas techniques.

As patent applications on barley show, the real legal uncertainties and costs incurred in this situation can block breeders from providing new varieties. In addition, breeders working for organic agriculture can be stopped from providing their own varieties even after decades of breeding.

*No Patents on Seeds!* is demanding that the interpretation of patent law is corrected without delay. The aim is to strictly confine the granting and the scope of patents to genetic engineering processes and to no longer hamper traditional breeding with patents.

## Introduction

Patents granted on seeds represent one of the biggest risks to global food security and regional food sovereignty. Patents create monopolies: plants and animals claimed in patents cannot be used by other breeders, gardeners or farmers for further breeding without the permission of the patent holder. In many cases, the patents also cover the use of the harvested plants for food production. 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.

*No Patents on Seeds!* is an international coalition that has been actively campaigning for over ten years to stop the increasing monopolisation of resources needed for food production. Its members are the Arbeitsgemeinschaft bäuerliche Landwirtschaft (AbL), ARCHE NOAH, BUND Naturschutz in Bayern (BN), Biorespect, Corporate Europe Observatory, Danish Seed Savers, Gen-ethical network (GeN), IG Nachbau, No Patents on Life!, Oxfam, ProSpecieRara, Public Eye, Plataforma Transgénicos Fora, SWISSAID and Munich Environmental Institute.

In June 2017, the Administrative Council of the European Patent Office (EPO) decided that patents covering plants and animals derived from essentially biological processes for breeding should no longer be granted: the new Rule 28(2) was introduced into the Implementing Regulations of the European Patent Convention (EPC). This decision was a huge victory for the interests of the wider public as well as for the numerous organisations represented in the international coalition of *No Patents on Seeds!*.

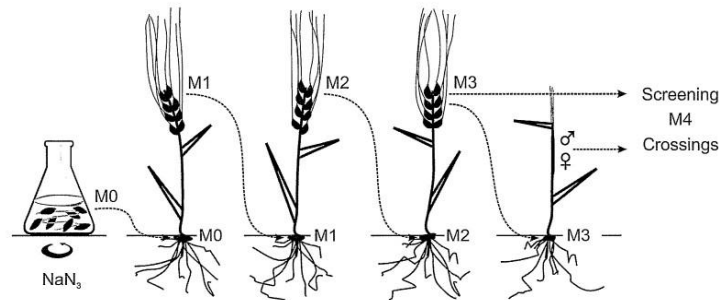
However, the decision was insufficient to really stop patents on conventionally bred plants and animals. Most crucially: there is no clear definition of “*essentially biological processes*”. The scope of patents is, in addition, not clearly restricted to technical methods. The consequences became clearly evident, e.g. in patents granted on conventionally bred barley.

Furthermore, a decision taken by the so-called Enlarged Board of Appeal (G3/19) in 2021 meant that the new Rule 28 (2) of the EPC would only apply to patent applications filed after 1 July 2017. This means that it might now take more than ten years until final decisions (after opposition and appeal procedures) are published. This, in turn, means that hundreds of further patents on conventional breeding might be granted within this period of time. Against this backdrop, politics needs to take action without delay.

## The Carlsberg patents

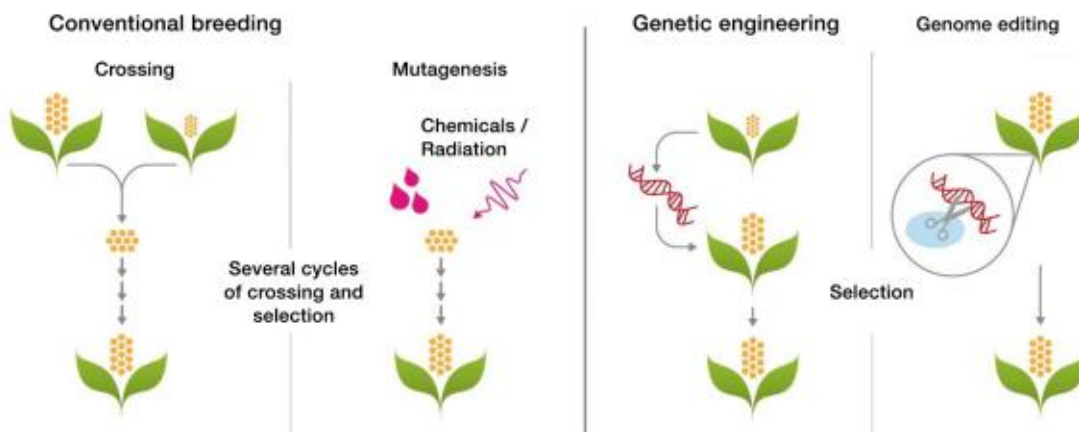
Carlsberg has filed several patents on barley and beer over the last few years, partly in cooperation with other companies, such as Heineken and Kronenbourg. It uses a simple method: the kernels are brought into contact with a chemical substance. This enhances the rate of mutations and genetic diversity. Crossing and selection are subsequently used to obtain the desired breeding characteristics in the plants (see Fig. 1).

Carlsberg has used this conventional method of plant breeding for about 90 years, it stems from a basic principle: plants are exposed to natural sunlight (UV radiation), which quite often causes genetic mutations to occur. These mutations are a chance for plants to generate genetic variations, which may allow a more rapid adaptation to changes in environmental conditions. In the case of the barley, sodium azide ( $\text{NaN}_3$ ) was used instead of sunlight to trigger a higher rate of mutations. These mutations may also emerge naturally, but only after longer periods of time.



**Fig. 1:** The breeding process for barley according to the Carlsberg patent applications: chemical substances are used to enhance the rate of mutations in the kernels. Further crossing and selection are used to subsequently obtain the desired traits.

The aim of genetic engineering approaches is to directly insert a trait into the plant genome. Using these techniques can also generate genetic alterations and genetic combinations (genotypes), which would only very rarely occur naturally, if at all. Therefore, these techniques are fundamentally different to those used in conventional breeding. According to patent law, such technical processes can be a patentable invention (see Fig. 2).



**Fig. 2:** Differences between conventional breeding (random mutagenesis) and genetic engineering (genome editing): conventional breeding typically needs several cycles of crossing and selection to achieve a desired trait; by contrast, genetic engineering is used to directly insert a trait into the genome.<sup>1</sup>

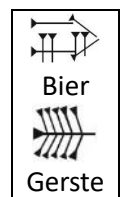
<sup>1</sup> Adopted from: Genomxpress Scholae Nr 5, funded by German ministry of Education and Research (BMBF).

Carlsberg has already filed around a dozen similar patent applications. To this end, the genome of barley was systematically screened for relevant genetic variations that may have useful traits. These include, for example, randomly induced mutations that influence the process of brewing and the flavour of the beer after storage. The EPO has already granted four patents, and oppositions have been filed against three of them by around 40 organisations.

Carlsberg appears to be aware of the problem that their barley is not actually patentable. It is likely that this is why techniques, such as CRISPR/Cas, are also mentioned in the patent. All the barley plants claimed in the patent are, in fact, derived from conventional breeding.

## The consequences

Barley and beer have been a part of human civilization ever since the times of the Sumerians and the Egyptians. The technique of brewing beer is considered to be a factor in the rise of the first urban civilizations: the Sumerians already had symbols for beer and barley 5000 years ago. Brewing beer is still considered to be an important part of our culture. Now, however, Carlsberg in particular, is trying to claim barley and beer as a technical invention and monopolize barley plants. The company is putting pressure on breeders, barley producers and other breweries by filing these patents, but consumers will also be affected by the consequences.



The impacts will also be felt by traditional breeders who have so far not had to worry about patents. According to the plant variety protection system, European breeders have free access to all varieties on the market. If they succeed in generating better varieties, they have their own, independent variety protection. They also have the exclusive right to sell their varieties, while other breeders can use the seeds for further breeding. Patents will hinder innovation within this process: as soon as a patent is granted on a plant, innovation could be blocked for twenty years (the duration of patents) because no other breeder is allowed to market new varieties with the patented characteristics.

A recent example shows the seriousness of the consequences: Cultivari is an organisation that breeds new varieties for organic agriculture. In 1997, the breeder, Karl-Josef Müller (who also founded Cultivari), was given a barley variety with a high content in amylopectin (specific content in starch) by a Japanese breeder. This trait causes a process called 'gelatinization' that starts at low temperatures when the kernels are used for brewing beer; this can save time and energy during the brewing process. Karl-Josef Müller started work on breeding a new variety in 1999, and in 2021 Cultivari was ready to start the process of registering a new variety. However, this is also when unexpected hurdles appeared: Carlsberg had, in fact, already filed a patent in 2019 on barley with similar characteristics caused by random mutations (WO2019134962).



The registration of a new variety is expensive and the expected market small and regionally localised. Therefore, it was necessary to find out whether there would be a conflict with the Carlsberg patent before starting the process of registering the variety. Based on the text of patent

application WO2019134962, this question could not be answered because the characteristics described in the patent were insufficient to draw final conclusions on a potential infringement. If a patent attorney had been consulted, this might have been even more costly than the income expected from selling the barley.

The breeder, Karl-Josef Müller, described his situation by saying: “After more than twenty years work of breeding barley, and just before we wanted to register our new variety in 2020, we discovered that Carlsberg had filed a patent application on barley with similar characteristics. Consequently, we would have had to shoulder not only the costs of registering our new variety, but also the costs of sorting out totally unforeseen legal questions. This is something we simply could not afford.”



**Photo:** Barley kernels of the variety of Cultivari

Cultivari has however been lucky: the Carlsberg patent application was withdrawn in early 2021. The reasons are not known, but Cultivari now is about to start the process of registering its variety.

This case shows how patents on seeds can hamper or completely block the development of new varieties. These negative impacts can also occur without any factual patent infringement. The reason: the technical and legal uncertainties associated with these patent applications incur substantial costs for laboratory analysis and patent lawyers, which are too high a hurdle for many breeders.

Not only breeders have taken action against these patents. For example, the executive director of the umbrella organisation of privately owned breweries in Germany (*Verband Private Brauereien Deutschland e.V.*), Roland Demleitner, told *No Patents on Seeds!* that they are generally against patents on barley and beer and are, in particular, against the Carlsberg patents. The Austrian breweries, Hirter and Zwettler, have even filed their own oppositions to one of the Carlsberg patents (EP 2575433).

## Patents on CRISPR & Co: the end of freedom in plant breeding

As recent patent research conducted by *No Patents on Seeds!* shows, big companies, such as BASF, Bayer, Corteva (previous DowDupont), KWS and Carlsberg, are systematically trying to exploit the existing legal loopholes as much as possible: these companies use specific wording in the patent applications in order to blur the differences between conventional breeding and genetic engineering processes (such as CRISPR/Cas) to obtain patents on conventional breeding. The research also shows that several such patents have already been granted in Europe.<sup>2</sup>

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2 Tippe, R., Eckhardt, J., Then, C. (2021) Stop patents on our food plants! Research into patent applications conducted in 2020 shows how the industry is escaping prohibitions in patent law. <https://www.no-patents-on-seeds.org/en/publications/report2021>

The gene scissors CRISPR/Cas enable more targeted genetic alterations compared to previous genetic engineering. The technology can generate complex genetic changes even without the insertion of additional genes.<sup>3</sup>

Contrary to any legal or scientific logic, the EPO largely supports the circumvention of prohibitions in patent law. A document written by the President of the EPO (CA/56/17)<sup>4</sup>, which is used in decision-making on patent applications, states that randomly triggered mutations should be considered to be equivalent to the processes of new genetic engineering (such as CRISPR/Cas & Co). Coincidentally, the EPO examination guidelines state that “Both targeted mutation, e.g. with CRISPR/Cas, and random mutagenesis such as UV-induced mutation are such technical [patentable] processes.”

It is remarkable in this context, that even UV radiation (such as sunlight) is explicitly named as a trigger of random mutations. Obviously no human intervention is needed in the case of sunlight. Consequently, independently of their origin, all mutations (environment, fields or laboratory) can be treated as technical inventions. This interpretation of patent law may affect the availability of thousands of plant varieties in near future.

Indeed, many patents make no differentiation between genetic engineering and conventional breeding. Rather, all plants with specific genetic characteristics are claimed as ‘inventions’, irrespective of how they were generated. In doing so, references are mostly made to the potential of the CRISPR/Cas technology, which, in theory, can be used to generate similar genetic mutations to those derived from conventional breeding. If such patents are granted, they cover all plants (or animals) with the described characteristics. This far-reaching scope of the patents is derived from something called ‘absolute product protection’. It means that if a patent is granted on a product, specific characteristics (no matter whether chemical, physical or genetic) and all products with the described characteristics (irrespective of how they were generated), fall under the scope of the patent. This problem cannot be solved by adding a disclaimer to restrict the scope of the patent. For example, the EPO may request ‘disclaimers’ in a patent stating that the scope of the patent does not extend to plants derived from ‘essentially biological processes’. However, since random mutations are considered to be ‘technical’ and not ‘essentially biological processes’, this wording would not exempt plants derived from random mutations.

As the example of the barley breeder shows, diversity, competition and innovation in traditional plant breeding can be substantially hampered, disrupted or blocked by these patents. By blurring the differences to the new genetic engineering techniques, the monopolistic claims and legal uncertainties can seriously impact traditional breeders. If this interpretation of patent law is continued, it will be the end of freedom to operate in plant breeding, despite this being guaranteed in the European plant variety protection system.

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3 For more detailed information see e.g.: <https://fachstelle-gentechnik-umwelt.de/en/home/>

4 [www.epo.org/modules/epoweb/acdocument/epoweb2/256/en/CA-56-17\\_en.pdf](http://www.epo.org/modules/epoweb/acdocument/epoweb2/256/en/CA-56-17_en.pdf)

## The demands

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

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 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.

As long as these problems are not solved, *No Patents on Seeds!* will continue to demand a moratorium on any further granting of patents in the field of plant and animal breeding.