Patents on CRISPR/Cas are threatening traditional breeding

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Summary

In June 2021, the EPO finally confirmed a patent (EP 2373154) on barley and declared the plants to be a patented invention. The barley, patented by company Carlsberg, was derived from conventional breeding methods and not genetically engineered. According to European patent law, only technical processes such as genetic engineering can be patented. However, the EPO is ignoring the legal provisions: According to a document, authored by the President of the EPO, random mutations are treated equal to genetic engineering processes. This interpretation was also applied in the case of the barley patent.

Indeed, in many patent applications no difference is made between genetic engineering and conventional breeding. Instead all plants with specific genetic characteristics are claimed as ‘inventions’, no matter how they were generated. Especially, the CRISPR/Cas techniques is frequently used to imitate results which originally are derived from by conventional breeding. If such patents are granted, they cover all plants (or animals) with the described characteristics. Thus, despite many breeders want to avoid genetic engineering, especially patents on the CRISPR/Cas techniques are increasingly becoming a threat for them.

As patent applications on barley show, the degree of legal uncertainties and costs being caused by this situation can block breeders from providing new varieties. Also breeders working for organic agriculture, can by stopped from providing their varieties after decades of breeding.

No Patents on Seeds! is demanding that the interpretation of patent law is corrected without any delay. The aim is, to strictly confine the grant and the scope of patents to genetic engineering processes and to no longer hamper traditional breeding by any 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!, as an international coalition, is active since more than ten years to stop the increasing monopolisation of resources needed for food production. Its members are Arbeitsgemeinschaft bäuerliche Landwirtschaft (AbL), ARCHE NOAH, BUND Naturschutz in Bayern (BN), Biorespect, Corporate Europe Observatory, Danish Seed Savers, Gen-ethisches Netzwerk (GeN), IG Nachbau, No Patents on Life!, Oxfam, ProSpecieRara, Public Eye, Plataforma Transgénicos Fora, SWISSAID and Umweltinstitut München.

In June 2017, the Administrative Council of the European Patent Office (EPO) decided that patents on 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). The 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 crucial: There is no clear defintion of *"essentially biological processes*". In addition, the scope of patents is not clearly restricted to technical methods. The consequences got evident e.g. in patents granted on conventionally bred barley.

Furthermore, in 2021 a decision of the so-called Enlarged Board of Appeal was published (G3/19) to apply the new Rule 28 (2) of the EPC only on patent applications being filed after 1st July 2017. It now might take more than ten years till final decisions (after opposition and appeal procedures) are published. Within this period of time, hundreds of further patents concerning conventional breeding might be granted. Before this background, politics has to get active without any delay.

The patents of Carlsberg

More than twenty years, company Carlsberg is active in filing patents on barley and beer, partially in cooperation with other companies such as Heineken and Kronenbourg. It is a simple method applied: The kernels are brought in contact with a chemical substance. Thereby, the rate of mutations and genetic diversity gets enhanced. Starting from there, further crosses and selections are performed till the desired breeding characteristics are achieved (see fig. 1).

The method as used by Carlsberg is applied since around 90 years in conventional plant breeding and is derived from a basic principle: Plants naturally are exposed to sunlight (UV radiation) which causes genetic mutations to occur quite often. For plants these mutations are a chance to generate genetic variations which may allow more rapid adoption to changes in the environmental conditions. In case of the barley, instead of sunlight, sodium azide (NaN_3) is applied to trigger higher rate of mutations. These mutations also may emerge naturally, but after longer periods of time.

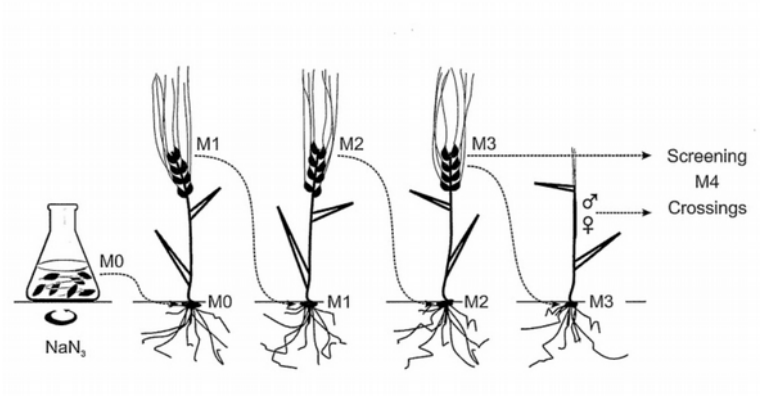


Fig 1.: The breeding process for barley according to the patent applications of Carlsberg: By using chemical substances, the rate of mutations in enhanced in the kernels. By further crossing and selection, desired traits may be achieved.

To the contrary, by applying genetic engineering, it is aimed to directly insert a trait into the pant genome. By these techniques also genetic alterations and genetic combinations (genotypes) can be generated which would hardly (if at all) may occur naturally. Therefore, these techniques are fundamentally different to those of conventional breeding. According to patent law, such technical processes can be a patentable invention (see fig. 2).

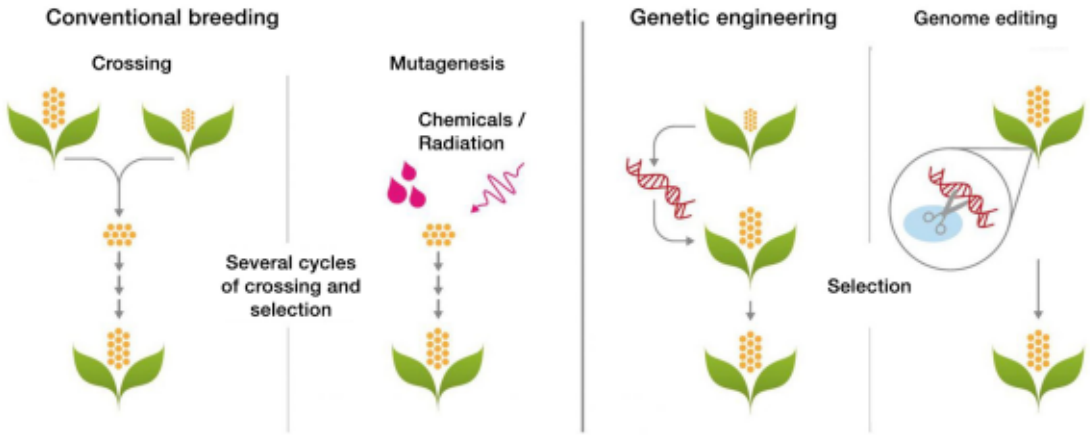


Fig 2.: Differences between conventional breeding (random mutagenesis) and genetic engineering (genome editing): Typically, conventional breeding needs several cycles of crossing and selection, to achieve a desired trait, while by using genetic engineering, a trait can be directly inserted into the genome.[1]

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, involving around 40 organisations.

The Carlsberg company seems to be aware of the problem that their barley is not patentable. That is why also techniques such as CRIPS/Cas are metioned in the patent. But in fact, all barley plants as claimed are derived from conventional breeding.

The consequences

Barley and beer are part of human civilisation since the times of old Sumerians and Egyptians. The technique of brewing beer is considered as important factor for rise of first urban civilisations, the sumerians, 5000 years ago, already had symbols for beer and barley.



Still today, brewing beer is considered as part of our culture. Now especially Carlsberg tries to claim barley and beer as an technical invention and to monopolize barley plants. By filing patents, the company is putting pressure on breeders, barley producers and other breweries, and also consumer are affected by the consequences.

Especially impacted are traditional breeders which so far had no need to care about patents. According to the plant variety protection system, European breeders have free access to all varieties being on the market. If they manage to generate better varieties, they can enjoy their own, independent variety protection. Then, they have the exclusive right to sell their varieties while other

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

breeders still can use the seeds for further breeding. Within this process, patents are acting as brakes to innovation: As soon as a patent is granted on a plant, innovation might become 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 show the severe consequences: The organisation Cultivari is breeding new varieties for organic agriculture. In 1997, the breeder Karl-Josef Müller (which also founded Cultivari) received a barely variety with a high content in amylopectin (specific content in starch) from a Japanese breeder. This trait causes that a process that is called ‘gelatinisation’ already starts at low temperatures if the kernels are used for brewing beer. This effect can spare time and energy during brewing. Already in 1999 Müller started breeding to generate a new variety. In 2021, Cultivari was ready to start the process for registering a new variety. But at this time, unexpected troubles showed up: In 2019, company Carlsberg had been filing a patent on barley with similar characteristics, caused by random mutations (WO2019134962).

The registration of a new variety is expensive and the expected market is supposed to be small and more regional. Therefore it was necessary to sort out if there could be a conflict with the patent of Carlsberg, before starting the process of variety registration. Based on the text of the patent application WO2019134962 as filed, this question could not be answered. The characteristics as described were not sufficient to draw final conclusions about a potential infringement of the patent. If a patent attorney would have been consulted, this might have been more costly than the expected income from selling the barley.

The breeder Karl-Josef Mueller described his situation: “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 unexpected legal questions. This is something we simply could not afford.”

In this case, Cultivari had great luck: Since early 2021, the patent application of Carlsberg is considered as being withdrawn. The reason for this are not known. Cultivari now is about to start the process for variety registration.

Photo: Gerstenkörner der Cultivari-Sorte

The 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 that are too high a hurdle for many breeders.

Not only breeders, but also brewers became active 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 the organisation is generally against patents on barley and beer and especially against the patents of Carlsberg. The Austrian breweries Hirter and Zwettler even have been filing own oppositions against one of the Carlsberg Patents (EP 2575433).

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

As recent patent research of *No Patents on Seeds!* shows, big companies such as BASF, Bayer, Corteva (previous DowDupont), KWS and Carlsberg systematically try to exploit the existing legal loopholes as far as possible: These companies, in their patent applications, use specific wordings which are meant to blur the differences between conventional breeding and genetic engineering processes (such as CRISPR/Cas), to gain patents on conventional breeding. As the research shows as well, several of such patents were already granted in Europe.[2]

In contradiction to any legal or scientific logic, this circumvention of prohibitions in patent law is largely supported by the EPO. In a document, authored by the President of the EPO (CA/56/17)[3], which is used in the decision making on patent applications, it is stated that mutations triggered at random should be considered as being equivalent to the processes of new genetic engineering (such as CRSPR/Cas & Co). In coincidence, it is stated in the examination guidelines of the EPO: „Both targeted mutation, e.g. with CRISPR/Cas, and random mutagenesis such as UV-induced mutation are such technical [patentable] processes."

It is remarkable, that in this context, just UV radiation (such as sunlight) is explicitly named as a trigger of random mutations. In the case of sunlight, not any human intervention is needed. In consequence, all mutations, independently from their origin (environment, fields or laboratory) can be considered as a technical inventions. This interpretation of patent law may affect the availability of thousands of plant varieties in near future.

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

The demands

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

The 'freedom to operate' is the precondition for the future of:

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

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

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

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

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

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

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

As long as these problems are not solved, *No Patents on Seeds!* demands a moratourium for further grant of patents in the field of plant and animal breeding.