

#### Q&A on plant patents

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#### Answers

#### 1. Why are there "plant patents"?

Developing plants with greater resistance to pests or environmental changes, that have a higher yield or more nutrients, or whose cultivation requires fewer resources such as water, fertiliser or pesticides is of the utmost importance in encouraging sustainable agriculture and ensuring food security. However, breeding enhanced plants is extremely time-consuming, involving considerable costs and risks. To facilitate research and development in this field and stimulate investment, the legislator has decided that inventions involving plants may be patented. At the same time, publishing patent applications gives third parties an opportunity to build on - and update - existing expertise on an ongoing basis.

# 2. But the law expressly states that plant varieties are excluded from patentability?

That's right. Patents are not granted for plant varieties. Varieties are certain subgroups of a plant species with special hereditary characteristics that distinguish them from other varieties. Granny Smith® and PinkLady® are varieties of apples, for example. Nonetheless, by prohibiting patents for plant varieties, the law does not exclude plants as such from patentability. Numerous inventions relating to plants, such as enhancing resistance to disease, are not restricted to certain varieties but may be applied to a great many plants. Therefore, these inventions and the plants to which they refer can generally be patented.

Plant varieties are protected by a different type of intellectual right, the Plant Variety Right. The <u>Community Plant Variety Office (CPVO)</u> is the EU agency responsible for managing the Community Plant Variety Rights System. The EPO has co-operated closely with the CPVO for many years.

#### 3. Can conventionally bred plants be patented?

Plants produced by breeding processes such as crossing and selection are not patentable. The EPO does not grant patents on these plants nor on the process applied. This breeding method is often referred to as "biological", "traditional", "standard" or "conventional", unlike genetic engineering methods, for example. The patent exemption also includes parts of biologically produced plants such as seeds, crops or other propagation material.

## 4. Why is the media full of reports on patented, traditionally bred peppers, tomatoes, melons and so on?

Under patent law, plants obtained by biological breeding processes were excluded from patentability with effect from 1 July 2017. However, the exclusion from patentability does not apply to patents filed before that date. This was expressly stipulated by the EPO's highest judicial authority, the <u>Enlarged Board of Appeal of the EPO</u>, and must be observed by the Office in examination practice. Known as non-retroactivity, this general principle of law ensures that actions taken in legitimate expectation in the applicable law prior to a legislative change are protected. This is also the case in other areas of law, such as tax law, criminal law and international law.

Roughly 300 proceedings are still pending at the EPO as they are covered by the principle of non-retroactivity and could thus lead to patents on plants obtained by biological breeding processes if all other patentability requirements are met. On the other hand, these media reports frequently mention patents that refer to plants produced by technical processes and not solely by the biological methods of crossing and selection. Plants obtained by technical processes are generally considered patentable under the law. This includes plants that have been genetically engineered or where a genetic modification (or mutation) of a plant is created by technical means.

## 5. Couldn't the exclusion from patentability for plants obtained by biological processes simply be circumvented by citing a technical intervention?

Legislation stipulates that the term "biological breeding process" is to be understood as meaning that engineered plants are not patentable. This definition has been further elaborated by the <u>EPO's independent judicial body</u> and is strictly observed by EPO patent examiners. Nonetheless, exclusion from patentability cannot be circumvented solely by citing the use of technical processes to breed the plant if the characteristic in question (e.g. higher yield) is created by means of crossing and selection. Conversely, the patent exemption does not apply if a trait is inserted in a plant or modified in situ via a technical intervention (e.g. "gene scissors"/CRISPR-Cas).

To ensure that patents on "plants made by technical methods" cannot be extended to plants that have been produced by biological processes and carry the same characteristics, the EPO requires that a "disclaimer" be included in the patent. Therefore, for the plant obtained by technical processes, the part of the patent that defines exactly what is to be protected (i.e. the claims) must specify that the patent does not include plants produced by biological means. This disclaimer applies to all applications filed since 1 July 2017. Under the principle of non-retroactivity, this does not apply to previous cases (see explanation above).

## 6. It is remarkable that "technical plants" can be patented if the characteristic in question already exists in nature or is established.

This is because simple discoveries are generally not considered patentable; this also applies to the plant kingdom. However, legislators have ruled that, where a plant has been obtained by technical processes, it may be considered patentable if the trait in question (e.g. colour, resistance to pests, yield, vigour etc.) was previously found in nature. The aim thereby is to encourage and recognise the discovery of incorporating the characteristic in a plant using a technical method and making the associated technical invention available to the general public, the development of which is usually faster and more systematic than a natural process and thus offers numerous benefits for plant breeding. At the same time, it must be taken into account that the fact of a natural plant characteristic being known or in existence may play a role when examining the criteria of *novelty* and *inventive step* of a claimed invention. Subject to these fundamental patentability requirements, a patent is only granted if an invention is new and not the obvious result of what is already known. To ensure that the EPO takes all relevant prior art into consideration when examining a patent, it also exchanges data with the Community Plant Variety Office (CPVO). This enables patent examiners to ascertain whether plants with a particular characteristic are listed in the CPVO protected plant variety database.

## 7. Can the owner of a "plant patent" ban others from all relevant activity and ultimately even gain access to the vegetables and beer in my fridge?

At first, a patent invariably only applies specifically to the claimed invention. "Plant patents" do not apply to all types of varieties of barley, peppers etc. and products thereof, in other words not to beer per se and so on. Moreover, the patent protection does not extend to products purchased by customers.

The patent owner can stop others, such as competitors, from manufacturing the patent-protected plant using technical processes and subsequently selling the plants thereby produced.

Due to an amendment of the law for the forthcoming introduction of the <u>Unitary</u> <u>Patent</u>, breeders will soon be given free use for their own breeds of plant material on which the EPO has granted a patent (known as breeders' exemption).

#### 8. Who decides on "plant patents"?

Legislation decides which inventions in the plant kingdom are considered patentable and which are not: the applicable law was passed by the EU (<u>Directive on the legal</u> <u>protection of biotechnological inventions</u>) or, to be more precise, by the 39 member states of the European Patent Organisation (European Patent Convention).

The EPO strictly follows the law in its <u>examination practice</u>. Patent applications are evaluated by a committee of three highly qualified technical members, in other words, by biotechnology experts specialising in plants and plant breeding in the case of "plant claims". In exceptional cases, an expert in patent law may be invited to consult as a fourth member. To grant a patent, it is not sufficient for an invention not to be excluded from patent protection. On the contrary, all other patentability criteria must be met, particularly novelty and inventive step. Furthermore, the applicant must

describe their invention in the patent application so comprehensively and clearly that an expert (e.g. a competitor) could understand and implement it. The fact that, as a rule, just half of the patents filed in Europe - and even less than 30% of biotechnology applications - lead to a patent being granted, shows that the EPO examination is extremely thorough.

It is important to bear in mind that anyone who considers that a particular patent should not have been granted can file an opposition to the EPO. The objections to granting the patent are then re-examined in a separate process by a new division of three or four specialised examiners. Should this division uphold the granted patent, the ruling may be contested once again before the EPO's independent judicial body (the Enlarged Board of Appeal). Moreover, patents granted by the EPO are subject to the judicial control of the national patent courts in the member states.

## 9. Are the "plant patents" used to forbid breeders (SMEs, breweries etc.) from continuing their developments?

Patent infringement proceedings fall within the remit of the national courts. To date, the EPO is not aware of any case in which the owner of a "plant patent" had banned breeders from carrying out experiments or had sued them for damages.

Under the statutory law in force since 1 July 2017, European patents on plants obtained by technical processes do not extend to plants with the same trait that were produced by biological means. Therefore, irrespective of the patented technical process, a plant breeder may generally cultivate the same plant by means of crossing and selection.

Having said this, due to an impending amendment of the law, the <u>Unitary Patent</u> will soon give breeders free use of EPO-patented plant material for their own breeds (breeders' exemption, see explanation above).

## 10. It often appears as though there are a great many "plant patents". Is this the case?

At the end of August 2022, the total number of European patent applications published since 1995 on conventional plants (including the instruments used for breeding) was just over 1 000. Of these cases, fewer than 100 European patents have been granted on plants obtained by biological breeding processes in over 25 years. Approximately 300 cases are currently pending at the EPO.

The vast majority of patent applications and patents granted for plants refer to genetically modified plants. Roughly 8 800 patents have been filed and around 3 100 patents granted in Europe since 1995.

For comparison: in 2021 alone, a total of over 188 000 patent applications were filed and almost 109 000 European patents were granted by the EPO in all areas of technology.

## 11. Will patents on genetically modified plants mean an increase in "GM" vegetables and fruit in my local supermarket?

A European patent, the examination and grant of which are the responsibility of the EPO, merely grants its owner the right to prohibit others, such as competitors, from commercialising the invention. However, a patent does not include a licence to

commercialise the patented invention, in other words, to market or cultivate a genetically modified patented plant. Patents do not entail approval of any kind. Licences to cultivate genetically modified organisms (GMO) or use them in food are subject to special European and national legal provisions, and are regulated by designated agencies (e.g. <u>EFSA - European Food Safety Authority</u>).

#### 12. Does the EPO comply with EU rules regarding "plant patents"?

In 1999, the EPO adopted the regulations of the <u>EU Biopatent Directive</u>, which address the patentability of plant varieties, in the European Patent Convention. The EPO takes the Directive and its recitals into account when examining a patent. This also refers to rulings issued by the European Court of Justice on the interpretation of the EU Biopatent Directive. This means that the EPO's practice and jurisprudence are in full compliance with the EU Biopatent Directive. At the same time, it should be noted that all EU member states are also contracting states to the European Patent Organisation.