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# LIFE SCIENCES UPDATE

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Patentability of Plants & Animals  
at the European Patent Office

# Patentability of Plants & Animals at the European Patent Office (EPO)

On 1 July 2017, the European Patent Office (EPO) amended the rules in relation to the patentability of products obtained from conventional breeding processes:

*'(2) Under Article 53(b), European patents shall **not be granted in respect of plants or animals exclusively obtained by means of an essentially biological process.**' (new Rule 28(2) EPC)*

This rule change by the EPO aims to harmonise the law in Europe relating to the patentability of products obtained from essentially biological processes, such as plants or seeds derived from conventional plant breeding processes.

## Prior to 1<sup>st</sup> July 2017

The EPO grants patents in accordance with the European Patent Convention (EPC) which lists exceptions to patentability, including for example, human cloning and use of human embryos.

For patents relating to biotechnological inventions, the EU Biotech Directive (Directive 98/44/EC) is also applicable and in 1999 this Directive became part of the EPC.

In Europe, the list of exceptions to patentability under [Article 53\(b\)](#) EPC includes:

*'(b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof.'*

It is established case law at the EPO, that transgenic plants which are novel and inventive are eligible for patent protection, once they are not directed to a particular plant variety. Furthermore, biotechnological processes used to make plants are also eligible for patent protection.

In recent years, the EPO Enlarged Board of Appeal (EBA), in Decisions G2/12 'Tomatoes I/II' and Decision G3/12 'Broccoli I/II', considered the patentability of plants and essentially biological processes for the production of plants. Following these EBA Decisions, in 2015, it was held that the products of conventional plant breeding processes **could be patented**. However, this ruling was controversial in Europe and there were some conflicting views around these EBA Decisions.

In November 2016, the European Commission (the EU administrative body) issued a Notice which stated:

*"the EU legislator's intention when adopting Directive 98/44/EC was to **exclude from patentability** products (plants/animals and plant/animal parts) that are obtained by means of essentially biological processes."*

This Notice contradicted the Decisions of the EBA in 'Broccoli II' and 'Tomatoes II'. However, this Notice was not directly binding on the EPO. Nevertheless, at that time, the President of the EPO placed a stay of proceedings on related cases.

Furthermore, the National laws of some EU member states, including Austria, France, Germany and the Netherlands, were amended at this time to prohibit patents directed to plants and animals derived from essentially biological processes. Thus, the National Laws of these EU member states were not in harmony with the EPC.

On 1 July 2017, the EPO Administrative Council changed the wording of Rule 28(2) EPC to prohibit the patenting of *'plants or animals exclusively obtained by means of an essentially biological process'*.

This appears to have been an attempt to harmonise the law in Europe to prohibit the patenting of products obtained from essentially biological processes, such as plants or seeds derived from conventional plant breeding processes. However, this may have resulted in a greater lack of clarity for applicants.

## Impact of these changes

A direct result of this rule change is that examination proceedings and opposition proceedings will now recommence on related cases.

Furthermore, it is likely that the interpretation of this rule change may be challenged in future examination or opposition proceedings on the basis that the EPC is interpreted by the EBA and not EU law. For example, a challenge could be made on the basis that the EPO Administrative Council when making this rule change did not make any reference to the EBA Decision G2/12 'Tomatoes II' and Decision G3/12 'Broccoli II'. These Decisions remain binding on the EPO when interpreting the EPC.

Furthermore, the meaning of the term '*exclusively*' in amended Rule 28(2) EPC is also open to interpretation as there is no agreed definition for this term. We expect this to be challenged in future examination or opposition proceedings.

## Practical advice for Applicants

Transgenic plants which are novel and inventive are eligible for patent protection, once they are not directed to a particular plant variety.

National Plant Variety Rights and Community Plant Variety Rights offer protection for plant varieties throughout Europe for which patent protection may not be applicable.

Biotechnological processes used to make plants are also eligible for patent protection.

It appears that conventional breeding processes for the production of plants or seeds are at present not eligible for patent protection under the EPC. However, National law now varies across the EU member states, thus, further clarity is needed. Until then, as a precautionary measure, we advise applicants to continue to include claims/description covering essentially biological processes for the production of plants or animals in their specifications.

## Further advice?

If you would like to learn more about this topic or have any queries on Patents or Plant Variety Rights, please contact the author Anna Hally, or any of the life science team at Hanna Moore + Curley.



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*For any further specific questions, please contact any one of our European Patent and Trade Mark Attorney team at Hanna Moore + Curley. This guidance document provides general information only and does not constitute legal advice.*

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