

no patents on seeds



Summary Note – Implementing the Commission’s Legal Notice

No Patents on Seeds!, April 2017

Background: European Commission Legal Notice

In November 2016, the European Commission published an Explanatory Notice on the interpretation of EU Directive 98/44/EC (“Biotech Directive”). In its conclusion, it states that:

“the Commission takes the view that 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.”

The Commission’s Notice followed two resolutions of the EU Parliament in 2012 and 2015. It was subsequently adopted by the EU Member States in February 2017.

According to the Notice, it is only possible to patent inventions involving the “genetic engineering” of plants and animals, such as “for instance the insertion of a gene into a genome”. Therefore, what is generally regarded as 'conventional breeding' cannot patented.

The Notice is a decisive step in helping to realise the prohibitions under Article 53(b) of the Directive, which exclude both “plant and animal varieties” and “essentially biological processes for breeding” from patentability. However, to render the Notice legally binding, it must be integrated into the rules and provisions of the European Patent Convention (EPC) that are applied by the European Patent Office (EPO). This can be accomplished by the Administrative Council of the European Patent Organisation (EPOrg), which has the ability to change the “Implementing Regulations” of the EPC by a majority vote.

Protect the interests of broader public!

In its practice to date, the EPO has consistently sought to circumvent the exclusions on the patentability of conventionally bred plants and animals. This tendency reflects the vested interest of the EPO: its significance as an organisation, and its budget, depends on the number of patents it grants. This bias is intensified by the fact that lobby groups representing the patent law profession (epi) and industry (BUSINESSEUROPE) attend EPO meetings, whereas representatives of consumers and broader civil society are excluded. We are also aware that EPO examiners already advise applicants on how to escape the exclusions by allowing patents on random mutations and genetic variants, as well as on the selection of plants and animals for further breeding.

We are deeply concerned that the EPO will now seek to limit the impact of the Commission’s Notice by promoting only minor and ineffective changes to the Implementing Regulations. These concerns have been reinforced by the recent proposal of the President of the EPO to the Patent Law Committee of the Administrative Council. It proposes a very general rule that plants and animals are not patentable “if exclusively obtained by means of an essentially biological process”. The proposal would fail to put an end to the patenting of conventionally bred plants and animals – the three main shortcomings are explained below.

Political decision makers must now prioritise the public interest and take steps to prevent large corporations such as Monsanto and Bayer gaining control over the resources needed for our food.

Summary: Necessary changes to the Implementing Regulations

“No Patents on Seeds!” has set out in detail the changes to the Implementing Regulations of the EPC that are necessary to effectively implement the EU Commission’s Notice¹. The changes also take account of our analysis of the most recent patent applications in this field².

This note summarises the key changes to the Implementing Regulations that are necessary to end the patenting of conventionally bred plants and animals and that are omitted from the proposal put forward by the President of the EPO:

1. **Definition of essentially biological processes**
2. **Definition of products**
3. **Limiting the scope of patents**

1. Definition of essentially biological processes

- **Implementing Regulations must clarify that “essentially biological processes” covers all conventional breeding processes, including the exploitation of random mutations and all steps used in the process such as selection and / or propagation.**

Essentially biological processes are not limited to processes that exclusively consist of “crossing and selection”, as suggested by the EPO. The selection and usage of genetic variants and random mutations as well as processes for propagation such as selfing are widely used in conventional breeding and cannot be understood as methods for genetic engineering.

This view is consistent with the European Parliament resolutions from 2012 and 2015, which called on the EPO “*also to exclude from patenting products derived from conventional breeding and all conventional breeding methods, including SMART breeding (precision breeding) and breeding material used for conventional breeding.*”

To illustrate the importance of a comprehensive definition of “essentially biological processes”: patents concerning random mutations, which the President of the EPO explicitly proposes to exclude from the definition, accounted for 65% of all patents granted on conventionally bred plants and animals in 2016. Without a comprehensive definition of “essentially biological processes”, the changes to the Implementing Regulations will fail to prevent future patents on conventionally bred plants and animals.

2. Definition of products

- **Implementing Regulations must clarify that all “products” used in or emanating from essentially biological processes are captured by the exclusion, including all plant/animal parts and genetic information.**

For the exclusion to be effective, it must apply to plants and animals in all their forms and parts used in, or derived from, conventional breeding. The Commission’s Notice clearly states that the exclusion

¹ Technical briefing: How should the exclusions in Article 53(b) be interpreted to make them effective? April 2017, attached.

² Patent applications on plants derived from conventional breeding 2016
<http://no-patents-on-seeds.org/en/information/background/patent-applications-2016>

from patentability applies to all “plants or plant materials (fruit, seeds, etc.) or animals/animal material”. “Material” also includes genetic information.

There is a growing trend in current patent applications to claim genetic information in the form of specific variants or random mutations. These applications try to escape the provisions of Article 53 (b) of the Directive by referring to Article 3(2), which states that “biological material which is isolated from its natural environment” might be regarded as an invention. However, the Commission has now confirmed that this Article cannot be understood as a means to circumvent Article 53(b). This must now also be made clear in the Implementing Regulations of the EPC. Otherwise, it will still be possible to receive a patent for genetic information which then extends to any use of the that information, including in conventional breeding, and to any plants and animals containing that information.

3. Limiting the scope of protection

- **Implementing Regulations must prevent “absolute product protection” on plants, which enables a patent on a plant or an animal derived from a technical process to extend to all conventionally bred plants with the same traits**

Restrictions on the scope of patents that may still be granted on inventions concerning plants or animals (such as patents on genetically modified plants) are necessary to prevent such patents from extending to conventionally bred plants and animals containing the same traits or breeding characteristics. This risk of this “overlap” is growing in light of the upcoming methods for genome editing. A clarification on this issue is therefore essential to “future proof” the Implementing Regulations.

Instead, patents concerning plants and animals must be restricted to process claims. This means that only the technical breeding process can be patented; not the plant or animal, plant/animal part, or the genetic information arising from it. Such a limitation would provide legal clarity and certainty for conventional breeders, being comparable and complementary to the breeders exemption as established in plant variety protection system: as long conventional breeders are not using methods for genetic engineering, gene editing, methods that enable a targeted introduction of a trait into plants or animals, or material derived there off, they do not have to worry about the patent system but have sufficient freedom to operate in their breeding activities.

Limiting the scope of product protection in regard to Article 53(b) is also in line with the European Parliament resolution of 17 December 2015 on patents and plant breeders’ rights which calls for introduction of full breeders’ exemption into patent law. Further, it is in line with the Decision of the Court of Justice of the EU C-428/08 on Monsanto as well as national patent legislation on nucleic acid-related inventions in Germany, France, Luxembourg, Italy and Poland.³

Annex: Technical briefing: How should the exclusions in Article 53(b) be interpreted to make them effective? Revised version, April 2017

³ See report of the Expert Group on “The development and implications of patent law in the field of biotechnology and genetic engineering”, published by the EU Commission (E02973), <http://ec.europa.eu/DocsRoom/documents/18604/attachments/1/translations/>