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Patentability of Plants: Update

EPO amends rules relating to patentability of plants obtained by essentially biological processes

As of **1 July 2017**, the EPO has amended the Rules implementing the European Patent Convention (EPC) to exclude from patentability plants and animals obtained exclusively by an essentially biological process. Processes that introduce or modify a trait in the genome, such as transformation or gene editing, and modified plants produced by these methods, remain patentable.

The rule change is intended to address what many saw as a loophole, providing patent protection for essentially biological processes (which are excluded from patentability in Europe), by allowing protection for their products.

The EPO had paused examination of cases in this area, in anticipation of the rule change. Applicants can expect these cases to be picked up again, and any claims defining plants produced by classical plant breeding steps to be refused.

The change to the rules is not without controversy, and may have created further uncertainty, as we explain here.

WHAT HAS CHANGED?

Patent eligibility of plants has long been a controversial and unsettled issue at the EPO. Recent decisions of the Enlarged Boards of Appeal (EBA), and in particular the "Broccoli" and "Tomatoes" decisions[1], briefly made the situation clearer. In particular, it was decided that although essentially biological process for the production of plants and animals are excluded from patentability, the products of these processes are not. Therefore, it was possible in principle to obtain patent protection for plants produced by classical breeding methods, and perhaps more commonly, for plants produced by a mixture of breeding and non-breeding (e.g., transformation) steps. Following the rule change, such plants will no longer be patentable in Europe.

This includes plants produced by so-called "SMART" breeding methods (Selection with Markers and Advanced Reproductive Technologies) using genetic markers such as SNPs. The Boards of Appeal have already made clear that a process does not escape from being considered "essentially biological" just because it contains a step of a technical nature (such as DNA sequencing) which assists with crossing or selection. We can expect the EPO to refuse to grant claims to plants produced exclusively by such breeding methods in the future.

Plants derived from processes with technical steps which give rise to the introduction or modification of a trait (e.g., transformation or gene editing) continue to be patentable, so long as the claims are not restricted to a single plant variety.

WHY HAS THE CHANGE BEEN MADE?

Many groups, particularly in the plant breeding sector, were unsatisfied by the EBAs decision. They consider that by granting patents to the products of these patents also prevent the use of the essentially biological processes, because carrying out that process would necessarily produce one of the patented products (potentially committing an act of patent infringement). This meant that even

though European patent law expressly prevents patents being granted to essentially biological processes, plant breeders would still be restricted from using them.

These groups successfully lobbied the European Parliament, encouraging them to ask the European Commission to look at this issue. In November 2016, the Commission issued a Notice regarding the interpretation of the EU Directive on Biotechnological Inventions (known as the "Biotechnology Directive"), concluding that the legislator had intended to exclude not only essentially biological processes but also the products obtained by those processes.

Following the issuance of the Notice, the EPO put on hold the examination of any patents which might be considered to relate to plant or animal varieties obtained by an essentially biological processes. They subsequently announced that the rules of the EPC were to be amended to contain an explicit prohibition on the patentability of plants obtained exclusively by an essentially biological process.

The new Rules came into effect on 1 July 2017, and are intended to have the immediate effect.

WHY IS THE CHANGE CONTROVERSIAL?

The move by the EPO, first to pause the examination of certain cases, and then to amend the rules, is controversial for various reasons.

The EPO is not an EU institution, and is not formally bound by the Biotechnology Directive. There is a "strong formal link" between the Biotechnology Directive and the EPC though, because the EPC legislator had previously decided, for reasons of harmonisation, to implement the provisions of the directive into the framework of the EPC2000[2]. Therefore, although the EPO is not required to implement changes to the Biotechnology Directive, it is not unexpected that it would do so.

However, the Commission Notice on "legislative intent" does not amount to a decision that is binding on EU member states, and it is certainly not binding on the interpretation of the EPC. Indeed, it is possible that the CJEU, who are responsible for interpreting EU treaties and directives, could take a different view to the Commission if the question comes before them in the future. Changing the rules in response to the notice may be premature.

It is also arguable that the amended Rules are not consistent with the Articles of the EPC, which state that patents shall be granted for any inventions, in all fields of technology (Article 52(1) EPC), subject to the exceptions of Article 53 EPC. Article 53 excludes essentially biological processes from patentability, but it does not mention the products of these processes, so the amended Rule arguable goes further than the Article. In the event of conflict between the Articles and the Rules, the Articles take precedence, and so by changing the Rule and not the Article, the change may not have the intended effect of clarifying the scope of the exceptions to patentability. Indeed, it is entirely possible the EBA could in future decide to uphold their original interpretation of the Articles, essentially negating the changes to the Rules.

We had hoped that we'd arrived at a settled interpretation about what is, and is not, patentable in this area, but it seems that the saga will continue.

FURTHER ADVICE

If you would like any advice about how this rule change may affect your application, then please get in touch with your usual contact, or with Frances Salisbury in our Manchester Office

Fran is a member of our agricultural science team, helping clients to obtain patents for plant related inventions and plant biotechnology, and plant variety rights under the UPOV convention.

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[1] Broccoli and Tomatoes I – G2/07 and G1/08; Broccoli and Tomatoes II – G2/12 and G2/13; http://www.epo.org/law-practice/case-law-appeals/recent/g130002ex1.html

[2] http://archive.epo.org/epo/pubs/oj99/8_99/8_5739.pdf

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