

EPO Stays Proceedings Over Patentability Of Plants And Animals

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While the U.S. is still sorting out “*natural products*” jurisprudence under 35 USC § 101, the **European Patent Office (EPO)** is wrestling with the patentability of plants and animals, and has [announced an immediate stay](#) on all patent examination and opposition proceedings in which the outcome “depends entirely on the patentability of a plant or animal obtained by an essentially biological process.” The stay was prompted by a recent Notice from the European Commission (EC) concerning Directive 98/44/EC on the legal protection of biotechnological inventions. In the Notice, the EC concluded that plants or animals derived from essentially biological processes are **not patentable** under the Directive. Until the EPO provides further guidance on this issue, applicants should exercise additional care in drafting the description and claims for inventions related to plants and animals.

Directive 98/44/EC

Directive 98/44/EC was adopted July 6, 1998, and arose from efforts to harmonize patent eligibility standards for biotechnological inventions among the different member states of the European Union. The Directive provides that the following inventions are not patentable:

- Plant and animal varieties (Article 4);
- **Essentially biological processes** for the production of plants or animals (Article 4);
- Human body and its elements (e.g., gene sequences) (Article 5); and
- Inventions whose commercial use contrary to *ordre public* or morality (e.g., processes of cloning human being, and processes for modifying the germ line genetic identity of human beings, uses of human embryos) (Article 6).

With respect to (2), Article 2 of the Directive defines essentially biological processes as processes consisting “**entirely of natural phenomena**, such as crossing or selection.” The Directive lays out a few examples of patentable subject matter, which appear to include microbiological products and processes (Article 4), biological materials possessing specific characteristics as the result of the invention and processes for the production of such biological materials (Article 8), and products containing genetic information (Article 9). However, the Directive does not specifically address the patentability of **products** made by essentially biological processes.

EPO Enlarged Board of Appeal Decisions

The recent attention to this issue was sparked by March 25, 2015 decisions from the EPO Enlarged Board of Appeal addressing the patentability of plants and plant parts produced by conventional breeding methods. The decisions were rendered in G 2/12 (“[Tomato II](#)”) and G2/13 (“[Broccoli II](#)”).

Tomato II involved EP Patent No. EP 1211926, which included the following exemplary product claims:

- A tomato fruit characterized by a capability of natural dehydration while on a tomato plant, natural



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dehydration being defined as wrinkling of skin of the tomato fruit when the fruit is allowed to remain on the plant after a normal ripe harvest stage, said natural dehydration being generally unaccompanied by microbial spoilage.

- A tomato fruit characterized by an untreated skin which permits dehydration of the fruit so as to obtain wrinkling of the skin, said dehydration being generally unaccompanied by microbial spoilage.

Broccoli II involved EP Patent No. EP1069819, which included the following exemplary product claim:

- A broccoli inflorescence having elevated levels of 3-methylsulfinylpropyl glucosinolates, or 4-methylsulfinylbutyl glucosinolates, or both; wherein the broccoli inflorescence is obtained from a hybrid plant following crossing of broccoli breeding lines with wild species and, the levels of 4-methylsulfinylbutyl glucosinolates, or 3-methylsulfinylpropyl glucosinolates, or both, are elevated above that initially found in broccoli breeding lines.

The Enlarged Board of Appeal rendered its decisions under Article 53(b) of the European Patent Convention (EPC), which prohibits patenting “plant or animal **varieties** or **essentially biological processes** for the production of plants or animals” with the exception of microbiological processes and products, and EPC Rule 27, which provides that plants or animals **are** patentable if the “technical feasibility of the invention is not confined to a particular plant or animal variety” (Rule 27(b)) or a product obtained by means of a technical process other than a plant or animal variety (Rule 27(c)).

After the Patentees canceled process claims reciting breeding methods, the Enlarged Board of Appeal upheld the patents with the product claims, explaining:

The exclusion of essentially biological processes for the production of plants in Article 53(b) EPC does not have a negative effect on the allowability of a product claim directed to plants or plant material such as plant parts.

The fact that the only method available at the filing date for generating the claimed subject-matter is an essentially biological process for the production of plants disclosed in the patent application does not render a claim directed to plants or plant material other than a plant variety unallowable.

The European Commission Notice on Patentability

In wake of the Enlarged Board of Appeal decisions, the European Parliament asked the EC to look into three issues related to the decisions:

- The patentability of plants and animals (and other products) derived from essentially biological processes;
- The issue of cross-licensing between patents and plant variety rights; and
- Access to deposited biological material, possibly by means of interpretative guidelines.

The EC addressed these issues in the [Commission Notice on certain articles of Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions](#) issued November 8, 2016.

On the first issue, the EC concluded that EU legislators intended to exclude plants and animals obtained by essentially biological processes from patentability, citing the Rapporteur’s statement in the Parliament’s report, as well as other provisions of the Directive:

“Essentially biological procedures”, i.e. crossing and selection of the whole genome [...] do not meet the general conditions for patentability, as they are neither inventive nor reproducible. ... **Patent protection is not appropriate for such procedures and their products.**

Thus, the Commission concluded that Directive 98/44/EC was intended to exclude plants/animals and plant/animal parts obtained by essentially biological processes.

More Uncertainty For Life Sciences

While the EC Decision makes clear that products made by genetic engineering **are** patentable, the EPO’s decision to stay proceedings involving a subset of applications and patents relating to plant and animal products creates more uncertainty for the life sciences industry. The EPO’s notice states that “[t]he effect of the Commission Notice for the EPO’s examination practice including any necessary follow-up measures is currently under

discussion with the representatives of the member states of the European Patent Organisation.” Thus, it seems likely that the stay will remain in effect until “the representatives” reach agreement on the impact of the Notice. In the meantime, it is not even clear when a proceeding will be deemed to depend “entirely” on the patentability of a plant or animal obtained by an essentially biological process so as to be subject to the stay. If an application or patent includes some such claims, could the stay be avoided by cancelling them?

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