

# Interpretation of European Patent Law by the European Patent Office

The European Patent Office (Enlarged Board of Appeal) decided on 25 March 2015 in two follow-up proceedings (G 2/12 – "Tomato II" und G 2/13 – "Broccoli II") that **plants and animals that result from essentially biological processes** may be patented even if their breeding method as such is not patentable. This EPO decision makes it clear that the amendment to the German patent law, according to which plants and animals resulting from essentially biological processes are excluded from patentability, will not be incorporated into the EPO's patenting practice when applying the European regulatory framework. The Federal Ministry of Justice and Consumer Protection (BMJV) and the Federal Ministry of Food and Agriculture (BMEL), which lead on patent law issues, are currently in the process of **determining scope for negotiation** in respect of the EU Commission and other Member States **with regard to amending the Directive on the legal protection of biotechnological inventions**.

General background note:

## Biopatents:

The patent laws in Germany and other EU Member States transpose the provisions of the European Patent Convention (EPC) and the EU Biotechnology Patents Directive (Directive 98/44/EC) into national law. These exclude plant varieties and animal breeds as well as "essentially biological processes" for the production of plants or animals from patentability.

Patents are granted for inventions which are new, which involve an inventive step and which are able to be used commercially. The holder of the patent is entitled to prohibit other persons or companies from using the patented invention or to make it subject to a licence fee. "Biopatents" are patents in the field of living matter. More precisely, this term refers to patents on plants or animals possessing specific characteristics, but also to patents on vaccines or diagnostics.

Depending on the desired scope, responsibility for the granting of patents, including biopatents, lies with the German Patent and Trade Mark Office (DPMA) or the European Patent Office (EPO). In the field of living matter, these authorities grant patents for

- **biological material** which is isolated from its natural environment or produced by means of a technical process,
- **plants or animals** if the technical feasibility of the invention is not confined to a particular plant variety or animal breed,
- **biotechnical procedures** or a product obtained by means of such a procedure, provided that it is not a plant variety or animal breed.

**It is fundamentally possible for patents to be granted** for inventions relating to biological material. 'Biological material' means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system (Section 2a (3) no 1 of the Patent Act). Under patent law, patents can also be granted to plants or animals possessing

characteristics modified by means of genetic engineering or other technical processes. Patent protection can also extend to the fruits of plants or to subsequent generations of animals (Section 9a of the Patent Act) and lead to licence fee obligations.

**Patents are not granted for**, among others, plant and animal varieties and essentially biological processes for the production of plants and animals and – in Germany – the plants and animals produced exclusively by such processes (Section 2a (1) no 1 of the Patent Act). These exclusions from patentability are due to the understanding that the continuous propagation of varieties and breeds represents a vital element of agriculture. Food security is dependent on constant access to a broad gene pool which should be restricted as little as possible by patents and other factors. From a patent law perspective, particularities in the field of plant breeding are taken into account by Section 11 no 2a of the Patent Act. This provision allows the use of biological material for breeding purposes in spite of any patents that may exist. The patent rights of the first breeder must only be considered when it comes to the exploitation of the products obtained through the further breeding.

## Decision on the "Broccoli patent"

With regard to the question as to what exactly can be understood by a non-patentable **"essentially biological process"** as compared to a patentable technical process, the EPO's Enlarged Board of Appeal announced on 9 December 2010 in its two key decisions G 1/08 (Tomato I) and G 2/07 (Broccoli I) that the mere use of technical steps to enable or assist essentially biological processes does not make them patentable.

The EPO's Enlarged Board of Appeal decided that classical breeding processes based on crossing and selection – including marker-assisted selection – fall under the exceptions to patentability under Article 53(b) of the European Patent Convention (EPC). The "Broccoli patent" is a patent on a specific variety of broccoli containing a particularly high level of glucosinolates, i.e. mustard oils which studies suggest can help reduce the risk of cancer. The patent protected a selection process to produce this broccoli variety. This process is characterised by determining the desired genes in the genotype and marking them with so-called genetic markers. The plants with the relevant properties are then selected with the help of the marker genes and used for breeding purposes.

Technical procedural steps used, e.g. a molecular marker, continue to be patentable as such. On the basis of this decision, the patent holders withdrew their process claims from their patent.

## Amendment to the German Patent Act

The Biotechnology Patents Directive does not clearly indicate whether plants and animals produced exclusively by "essentially biological processes" are also excluded from patentability as products. In 2013, the German Bundestag amended the German Patent Act with the aim of fully enforcing the whole purpose of the Biotechnology Patents Directive, i.e. the exclusion of traditional breeding methods from patentability, and of preventing an evasion of the law to the disadvantage of breeders and farmers. To clarify the precise meaning of the Biotechnology Patents Directive, section 2a (1) no 1 of the Patent Act was amended to include the provision that plants and animals produced exclusively by such (essentially biological) processes are also excluded from patentability. This also applies to the material intended for their production such as seeds, semen, ova and embryos.

The largely free access to genetic resources is a basic prerequisite for the work of breeders and farmers. In this light, the amendment to the German Patent Act, fully exhausting the national possibilities in respect of interpreting the EU Biotechnology Patents Directive, is an important first step, sending a signal in respect of European patent granting practice.

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## Biopatent monitoring

With the help of biopatent monitoring, the Federal Office for Agriculture and Food (BLE) and the Federal Office of Plant Varieties (BSA), which have been charged with the patent research work for the Federal Ministry of Agriculture (BMEL), register and analyse the relevant patents in the fields of arable crops and farm animals. They sometimes have to deal with fundamental questions such as: In which fields are there a lot of patents? Where and how might intervention be necessary? Will it be sufficient to interpret the applicable patent law in a restrictive way? Are legislative changes required?

With its cross-party decision to exclude conventionally bred animals and arable crops from patenting, the German Bundestag asked the federal government in February 2012, inter alia, to establish a **national Biopatent Monitoring System** to be able to identify developments as early as possible and, in this connection, to submit a report every two years on the impact of the patent law in the field of biotechnology, e.g. with regard to sufficient technicality and on the impact in the field of plant and animal breeding.

The Federal Ministry of Justice and Consumer Protection (BMJV) leads on the federal government report due to its competence for patent law issues. The **BMEL Biopatent Monitoring System**, established in July 2012, is based on the relevant patent research and assessment work of the Federal Office of Plant Varieties (BSA) in the field of arable crops and of the Federal Office for Agriculture and Food (BLE) in the field of farm animals.

The first federal government report to the German Bundestag was adopted by the cabinet on 9 July 2014 and then submitted to the Bundestag (BT-Drs. 18/ 2119).

In the 2013 reporting period, the figures on patents granted, patent applications published and patents deserving observation are unspectacular. The monitoring is focused on patents granted as only these can have an impact on agriculture and breeding.

It was not possible to identify any particular trends with regard to the questions posed by the Biopatent Monitoring System (constant access to a broad gene pool with minimum restrictions particularly with a view to ensuring food security, ensuring that breeders and farmers are not put at a disadvantage due to a gradual undermining of the exclusions from patentability), due in part to the small number of cases during the reporting period. There are no plans to exert influence on individual patent grant procedures.