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Regarding the patentability of plants and animals in Europe – the G 3/19 decision (*"Pepper"*) of the European Patent Office
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On May 14, 2020, the Enlarged Board of Appeal of the European Patent Office (EPO) decided that excluding *"essentially biological processes for the production of plants or animals"* from patentability pursuant to Art. 53(b) EPC is to be understood and applied in such a way that products that can be exclusively obtained by means of an essentially biological process are not patentable either. Accordingly, European patents on plants, plant material or animals exclusively obtained by means of an essentially biological process will no longer be granted as a matter of principle.

1. Background and referred questions

In the past, the Enlarged Board of Appeal already dealt with the question of the scope of the exclusion effect for patentability under Art. 53(b) EPC on several occasions. Particularly in the two more recent decisions G 2/12 und G 2/13, both issued in March 2015, the Enlarged Board of Appeal concluded that plants and plant material are not excluded from patentability even if they can be exclusively produced by means of an essentially biological process. This construction was opposed by the legal situation in some member states, including Germany. In October 2013, the German Patent Act (*PatG*) was amended to also exclude animals and plants exclusively produced by means of an essentially biological process from patentability.

Subsequently, in November 2016, the European Commission published a notice (2016/C 411/03) on the construction of the Directive 98/44/EG, the biotechnology directive of the European Union (EU). In said notice, the Commission took the view that, when the EU biotechnology directive was granted, the EU legislator had intended to exclude products obtained by means of essentially biological processes from patentability. Thus, the construction of Art. 53(b) by the Enlarged Board of Appeal was (also) contrary to the construction of the biotechnology directive by the EU Commission.

However, the notice 2016/C 411/03 does not have any legal effect, and, in particular, has no binding effect on the EPO, an institution independent of the EU. In order to harmonize EPC law with the law in force in many EPC member states, e.g. EU law, the Administrative Council of the EPO nevertheless decided in June 2016 to add the following paragraph (2) to Rule 28 of the Implementing Regulations to the EPC:

> *"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."*

However, due to the hierarchy of norms between the EPC and the Implementing Regulations to the EPC (cf. Art. 164 (2) EPC), there were doubts that Rule 28 (2) of the Implementing Regulations to the EPC could justify an extension

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of the scope of application of Art. 53(b) EPC contrary to the previous construction of this article by the Enlarged Board of Appeal. Accordingly, in the decision T 1063/18, one of the EPO's Technical Boards of Appeal found in December 2018 that Rule 28 (2) of the Implementing Regulations to the EPC was in conflict with the EPC and did not apply the rule.

Against this background, in April 2019, in order to *"establish uniform application of the law and certainty of the law"*, the President of the EPO submitted two questions for assessment to the Enlarged Board of Appeal, which the Enlarged Board of Appeal reworded and summarized in one question as follows:

> *„Taking into account developments that occurred after a decision by the Enlarged Board of Appeal giving an interpretation of the scope of the exception to patentability of essentially biological processes for the production of plants or animals in Article 53 (b) EPC, could this exception have a negative effect on the allowability of product claims or product-by-process claims directed to plants, plant material or animals, if the claimed product is exclusively obtained by means of an essentially biological process or if the claimed process feature defines an essentially biological process?"*

2. The decision

a. Problems concerning the admissibility of the submission to the Enlarged Board of Appeal

Beyond the significance of decision G 3/19 for substantive patent law, the referral to the Enlarged Board of Appeal by the President of the EPO also raised questions concerning the admissibility of bringing about a decision in this way. The implications of the proposal for the separation of powers within the EPO were critically discussed prior to the decision (cf. e.g. Haedicke in GRUR Int. 2019, 885).

Questions referred to the Enlarged Board of Appeal are governed by Art. 112 EPC. According to Art. 112(1)(b) EPC, the President of the EPO may, in order to ensure uniform application of the law or when a question of law of fundamental importance arises, refer a question of law to the Enlarged Board of Appeal if two Boards of Appeal have issued diverging decisions on that question.

In its decision, the Enlarged Board of Appeal assumed both (i) the existence of a question of law of fundamental importance and (ii) the existence of diverging decisions of two Boards of Appeal. With regard to condition (ii), it did not rely on deviations from decisions on the substantive scope of Art. 53(b) EPC, but on different methodological approaches in assessing the effect of a subsequently inserted provision in the Implementing Regulations to the EPC on the construction of an EPC standard.

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b. The Enlarged Board of Appeal's answer to the referred question

The Enlarged Board of Appeal now answers the reworded question of the President of the EPO, in deviation from its previous construction of Art. 53(b) EPC and by applying a so-called *"dynamic interpretation"*, as follows:

> *„Taking into account developments after decisions G 2/12 and G 2/13 of the Enlarged Board of Appeal, the exception to patentability of essentially biological processes for the production of plants or animals in Article 53 (b) EPC has a negative effect on the allowability of product claims and product-by-process claims directed to plants, plant material or animals, if the claimed product is exclusively obtained by means of an essentially biological process or if the claimed process features define an essentially biological process.*
>
> *This negative effect does not apply to European patents granted before 1 July 2017 and European patent applications which were filed before that date and are still pending."*

Accordingly, going beyond the wording of Art. 53(b) EPC and in accordance with the construction of the EU biotechnology directive by the EU Commission, plants, plant material and animals exclusively obtained by means of an essentially biological process are also excluded from patentability in future.

However, under a transitional arrangement provided for by the Enlarged Board of Appeal, the exclusion from patentability only applies to patents granted after June 30, 2017 and to patent applications filed after June 30, 2017. This also means that the protection of confidence is not provided for patents granted after July 1, 2017, for example following the decision T 1063/18 and before the submission in April 2019.

Comment: What is still patentable in Europe now?

Against the background of the decision of the Enlarged Board of Appeal, the question arises as to which possibilities still exist for animal and plant breeders to obtain patent protection for their breedings at the EPO – and in the EU.

The current assumption in this field is that only products obtained by a process involving a technical step resulting in a modification of the genome of the plant or animal are patentable. This step may not be a mere technical aid for the crossing or selection process.

A key term of Art. 53(b) EPC is the *"essentially biological process"*. In the decision G 3/19, the Enlarged Board of Appeal reiterates once again what is meant by this. Accordingly, an essentially biological process for breeding plants is characterized as follows:

- The process is not microbiological.

- The sexual crossing of whole plant genomes and the subsequent selection of plants are included as process steps.

- Crossing or selection can be enabled or improved by a *"step of a technical nature"*. This *"step of a technical nature"* can be created independently as a supplement or as part of the crossing or selection process.

Analogous requirements are placed on an essentially biological process for breeding animals (cf. EPO Guidelines for Examination, G.II.5.4 and e.g. Benkard, European Patent Convention, 3rd ed. (2019), marginal no. 106 on Art. 53 EPC).

On the other hand, a process is not covered by the exclusion from patentability under Art. 53(b) EPC if it comprises *"an additional step of a technical nature, which stepby itself introduces a trait into the genome or modifies a trait in the genome"*, i.e. if the introduction or modification is not the result of the crossing.

Determining whether a plant or animal is obtained by exclusively biological means entails examining whether there is a change in a heritable characteristic of the claimed organism which is the result of a technical process exceeding mere crossing and selection (cf. EPO, G.II.5.4). Thus, using only a technical aid for the crossing or selection process, such as a selection marker for example, does not generally overcome the element of exclusion.

On the other hand, a technical step which overcomes the exclusion from patenting is conceivable in particular as a process which itself leads to a modification of the genome within the germ cells of plants or animals. Both targeted mutations established with the help of the CRISPR/Cas9 technology for example, as well as random mutagenesis, such as UV-induced mutations are technical processes that allow patenting. When looking at the offspring of transgenic organisms or mutants produced in this way, if the mutation or transgene is present in said offspring it is not produced exclusively by an essentially biological processand is thus patentable.

For the assessment of patentability, it is irrelevant whether the *"step of a technical nature"* is novel, known in the art or trivial, whether it can also occur in nature or whether it is the central element of the invention. However, it must be essential for the modification of the plant or animal.

In addition, technical aids for crossing and selection are of course patentable themselves as long as they meet the general requirements for patentability, i.e. they are in particular novel and inventive.