

INVENTION PATENTABILITY: PLANT BREEDING

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According to Article 53(b) of the European Patent Convention (EPC), “essential biological processes” for the production of plants and animals are excluded from patent protection.

The term “essentially biological” is somewhat unclear. Rule 26(5) EPC, which is a result of incorporating the provisions of the EU Biotechnology Directive into the EPC, states that “a process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection”.

Even though this rule serves to define the terms of Article 53(b) EPC, it is somewhat ambiguous. This was made clear during the proceedings of the Enlarged Board of Appeal (EBoA) decisions, G2/07 and G1/08. These decisions said that crossing and selection as such are not entirely natural phenomena, but processes that involve human intervention.

In the broccoli case, G2/07, the EBoA was asked to consider whether a method for breeding broccoli plants, which contains the steps of crossing and selecting plants, escaped the exclusion of Article 53(b) EPC because the claimed method contains additional steps of a technical nature. This case was combined with G1/08 relating to the production of tomato plants with elevated water content.

In the broccoli case, features were added to the claims relating to the use of molecular markers, which assist in the selection of plants comprising the desired traits, and the use of double haploid breeding lines, which are the product of a technical process. Similarly, the claims in the tomato case included a step, which requires leaving the tomatoes on the vine past normal ripening, to assess which plants have the desired characteristics.

In both cases, the proprietors argued that these additional features were technical steps, requiring deliberate human action, and that the phrase “consists entirely” in R26(5) EPC means that the provision of steps that are different to crossing and selection steps make the method patentable.

However, the EBoA decided that since crossing and selection necessarily involve human intervention, the conclusion to be drawn was that a process for the production of plants that is based on the sexual crossing of whole genomes and on the subsequent selection of plants, in which human intervention, including the provision of a technical means, serves to enable or assist the performance of the process steps, remains excluded from patentability as being essentially biological within the meaning of Article 53(b) EPC. On this basis, if the claimed process is a process for obtaining plants based on sexual crossing and selection, then it is not patentable, irrespective of what other steps may be included in the claim.

“ANY ADDITIONAL TECHNICAL STEP PERFORMED EITHER BEFORE OR AFTER THE PROCESS OF CROSSING AND SELECTION SHOULD BE IGNORED WHEN DETERMINING WHETHER OR NOT THE PROCESS IS EXCLUDED FROM PATENTABILITY UNDER ARTICLE 53(B) EPC.”

However, the EBoA did leave an opening for patentability. It stated that if a process of sexual crossing and selection includes within it an additional step of a technical nature, and the step on its own introduces a trait into the genome or modifies a trait in the genome of the plant produced so that the introduction or modification of that trait is not the result of mixing the genes of the plants chosen for sexual crossing, then that process is no longer plant breeding, which the legislator wanted to exclude from patentability. Therefore, such a process is not excluded from patentability under Article 53(b) EPC but qualifies as a potentially patentable technical teaching.

The EBoA pointed out that this additional step is to be part of the crossing and selection procedure. Any additional technical step performed either before or after the process of crossing and selection should be ignored when determining whether or not the process is excluded from patentability under Article 53(b) EPC. Otherwise, the EBoA said, it would be too easy to circumvent the exclusion.

According to the decisions in question, a step that is part of a crossing and selection procedure may make a process patentable if it “by itself”—whatever that means—introduces a trait into the genome or modifies a trait in the genome of the plant produced. This is so long as the introduction or modification of that trait is not the result of mixing the genes of the plants chosen for sexual crossing. This implies that biological processes for breeding plants will only be patentable if they include a step that genetically influences the offspring.

In this respect, the position taken by the referring Technical Boards of Appeal in the corresponding broccoli and tomato cases will be important to interpreting the exclusion in Article 53(b) EPC. Oral proceedings in both cases are, at the time of writing, scheduled to be held on October 26, 2011. ■

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