

Broccoli (G 2/07) and Tomatoes (G 1/08)

The consolidated Decision of the European Patent Office (EPO) Enlarged Board of Appeal in the matters of G 2/07 and G 1/08 has issued. This Decision attempts to determine the meaning of “essentially biological” in the context of “essentially biological processes for the production of plants” within Article 53 EPC and Rule 26(5) EPC¹.

This issue has been looked at previously by the Technical Boards of Appeal at the EPO. Notably, in T 320/87, the Technical Board decided that the necessity for human intervention alone in a process is not a sufficient criterion for it being “essentially biological”. In T 356/93, the Technical Board found that a process for the production of plants comprising at least one essential technical step, which cannot be carried out without human intervention and which has a decisive impact on the final result, does not fall under the exceptions to patentability under Article 53(b) EPC.

Unclear and contradictory: the Enlarged Board’s view on the law

In discussing Rule 26(5) EPC, the Enlarged Board found that the wording of Rule 26(5) EPC is ambiguous, if not contradictory. The Enlarged Board looked to the text of the Biotech Directive for clarification of the meaning to be given to Rule 26(5) EPC and noted that the wording of the text as finally enacted by the Council is unclear and contradictory, even in view of the legislative history of the Biotech Directive, from which it is not possible to determine what the legislator intended. In conclusion of all of their analysis, the Board found that Rule 26(5) EPC does not give any useful guidance on how to interpret the term “essentially biological process for the production of plants” in Article 53(b) EPC. They considered that this term must be interpreted on its own authority and that this was a task for the Enlarged Board to do.

Some of the findings of the Enlarged Board

1. “Essentially biological processes for the production of plants” cannot be read as being limited to processes for the production of plant varieties.
2. It is not appropriate to draw a comparison between Article 52(4) EPC in relation to methods of treatment by surgery and therapy and the provision of Article 53(b) EPC. In this sense, whilst the mere presence of a method of treatment step in a claimed method will exclude the entire method from being patentable, the presence of one biological feature in a process cannot automatically confer an essentially biological character on the process as a whole.

¹ Article 53(b) EPC stipulates that European patents shall not be granted in respect of plant or animal varieties or essentially biological processes for the production of plants. This provision does not apply to microbiological processes or the products thereof.

Rule 26(5) EPC recites: a process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection. This wording is the same as Article 2(2) of the European Biotech Directive.

4. It also is not appropriate to draw an analogy with the computer-related inventions approach where “any technical means” makes the claimed subject-matter escape the exclusion under Article 52(2) EPC. The presence of at least one clearly identified “non-biological” process will not render a method claim allowable.

5. In order to give legal certainty, the decision whether a process is technical or essentially biological should not depend on what was already known or used in the art or on how far the claimed subject matter went beyond that.

6. The Technical Board in T 320/87 was fundamentally correct in its starting point that not just any kind of human intervention can suffice to make an invention in this field escape the exclusions.

7. The legislative intention was that the mere fact of using a technical device in a breeding process should not be sufficient to give the process as such a technical character and should not have the effect that such a process is no longer excluded from patentability. The legislator expressly indicated that it was sufficient for such devices to be patentable in themselves.

The Conclusion

The Enlarged Board stated that in, more general terms, the conclusion to be drawn is that a process for the production of plants which 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.

However, if a process of sexual crossing and selection includes within it an additional step of a technical nature, which step by itself 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 the mixing of the genes of the plants chosen for sexual crossing, then that process leaves the realm of the plant breeding, which the legislator wanted to exclude from patentability. This applies only where such additional step is performed within the steps of sexual crossing and selection, independently from their number of repetitions. Otherwise the exclusion of sexual crossing and selection processes from patentability under Article 53(b) EPC could be circumvented simply by adding steps which do not properly pertain to the crossing and selection process, being either upstream steps dealing with the preparation of the plant to be crossed or downstream steps dealing with the further treatment of the plant.

Practice Points

Following this decision, consideration must be given when drafting patent applications in this technical area to the recitation of an additional step of a technical nature in any claimed process of sexual crossing and selection. In time, case law will emerge from the

EPO Technical Boards of Appeal, providing guidance on what might be considered to be such an additional step.

The precise questions referred to the Enlarged Board and the Enlarged Board's answers in reply can be found by following these links:

[http://documents.epo.org/projects/babylon/eponet.nsf/0/E72204692CFE1DC3C12577F4004BEA42/\\$File/G1_08_en.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/E72204692CFE1DC3C12577F4004BEA42/$File/G1_08_en.pdf)

[http://documents.epo.org/projects/babylon/eponet.nsf/0/791D677646A4A968C12577F4004C3445/\\$File/G2_07_en.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/791D677646A4A968C12577F4004C3445/$File/G2_07_en.pdf)