

Patentability of essentially biological processes

The Enlarged Board of Appeal at the European Patent Office has recently given a ruling concerning the patentability of essentially biological processes in consolidated proceedings relating to two separate European patents (the so-called Tomato and Broccoli cases, G1/08 and G2/07, respectively).

Introduction

The European Patent Convention 2000 in Article 53(b) indicates that European patents shall not be granted in respect of essentially biological processes for the production of plants and animals (this provision does not apply to microbiological processes or the products thereof). Rule 26(5) EPC further defines 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. However, it was not previously clear to what extent a process which contains steps of crossing and selection could avoid the exclusion from patentability by including any other feature of a technical nature. This was one of the questions referred to the Enlarged Board of Appeal in the Tomato and Broccoli cases.

The tomato patent

The claim at issue in this case was directed to a method for breeding tomato plants with reduced fruit water content. The method involved steps of crossing two different plant species and various selection steps. Additionally, the method included a step of allowing the fruit to remain on the vine past the point of normal ripening and screening for reduced fruit water content. It was argued that the method fell outside the exclusion

since the crossing step involved special intervention as the different species are not generally capable of interbreeding and the selection step for reduced fruit water content would not occur in nature.

The broccoli patent

The claim at issue related to a method for the production of Brassica oleracea with elevated levels of particular glucosinates. The method involved steps of crossing a wild Brassica species with broccoli double haploid breeding lines and several selection steps. Further, it was indicated that molecular markers are used in the selection steps to select hybrids with elevated expression levels of the glucosinates. It was argued that the method fell outside the exclusion since the use of molecular markers requires removal and analysis of plant tissue, non-natural starting material is used in the double haploid strains and wild Brassica would not hybridise with Broccoli breeding lines unless brought together by human intervention.

Questions referred to the Enlarged Board of Appeal

It needed to be clarified whether it was possible to avoid the exclusion from patentability for an essentially biological process by including any other feature of a

technical nature, in addition to the crossing and selection steps. If it was not possible to avoid the exclusion by including an additional technical feature, then the criteria for distinguishing excluded processes from those not excluded needed to be established i.e. were some technical features sufficient to avoid the exclusion and others not. Particularly, it needed to be established if the technical feature should contribute something beyond a trivial level i.e. does the technical feature need to relate to the essence of the invention.

Findings of the Enlarged Board

The Enlarged Board decided that Rule 26(5) EPC was contradictory since crossing and selection in plant breeding are not natural phenomena as indicated in the Rule. After immense discussion, this Rule was not taken into account in interpreting the extent of the exclusion from patentability. The Board therefore decided how to interpret the exclusion on its own authority. It was decided that processes which contain steps of sexually crossing whole genomes of plants and selecting plants are in principle excluded from patentability, even if such processes contain a further technical step which assists or enables the performance of those steps. However, if the process contains within the steps of crossing and selecting, an additional step of a technical nature which introduces a trait into the genome or modifies a trait in the genome where the introduction or modification of the trait is not the result of the mixing of genes of the plants used for sexual crossing, then the process is not excluded. Finally, it was indicated that the technical step does not need to relate to the essence of the invention - it can be trivial.

Practical impact of the decision

The impact of the decision is quite severe for pending or new applications relating to the production of plants (or animals) which are based on crossing and selection steps. It is clear that for patentability a significant step of human intervention is required which takes the process beyond being a process based solely or principally on crossing and selection. In practice, it is likely that a step of genetic modification within the initial crossing step and the selection steps of the claims may be necessary. This decision is therefore likely to exclude from patentability even extremely technical plant breeding methods and hence, many more applicants will need to consider instead applying to the Community Plant Variety Office for protection for any new plant varieties generated.

Further advice

For further advice please contact us at Dehns using the details below.

More detailed information on the above and other biotech inventions may be found in the Dehns' booklet on "Patenting of medical and biotech inventions" which is available from our website [here](#).



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