

### 3.4. Microbiological processes and the products thereof

The exception to patentability for plant or animal varieties or essentially biological processes for the production of plants or animals does not apply to microbiological processes or the products thereof (Art. 53(b), second part of sentence, EPC).

#### 3.4.1 The concept of "microbiological processes"

R. 26(6) EPC defines a "microbiological process" as any process involving or performed upon or resulting in microbiological material. The boards have not yet issued a decision interpreting this definition.

According to T 356/93 (OJ 1995, 545), the concept of "microbiological processes" under Art. 53(b), second part of sentence, EPC refers to processes in which micro-organisms (or their parts) are used to make or to modify products or in which new micro-organisms are developed for specific uses. Consequently, the concept of "products thereof" under Art. 53(b), second part of sentence, EPC encompasses products which are made or modified by micro-organisms as well as new micro-organisms as such. The board defined the term "micro-organism" as including not only bacteria and yeasts, but also fungi, algae, protozoa and human, animal and plant cells, i.e. all generally unicellular organisms with dimensions not visible to the naked eye which can be propagated and manipulated in a laboratory, including plasmids and viruses.

Examining the patentability of the claimed plant grouping, the board in T 356/93 also addressed the issue whether **multi-step processes** for producing plants which include at least one **microbiological process step** could be considered as a whole to represent "microbiological processes", and whether, consequently, the products of such processes (e.g. plants) might be regarded as being "the products thereof" for the purposes of this provision. The board held that "technical processes including a microbiological step" could not simply be equated with "microbiological processes". Nor could the resulting final products of such a process (e.g. plant varieties) be defined as "products of a microbiological process" within the meaning of the said provision.

#### 3.4.2 Difference between microbiological and genetic-engineering processes

In G 1/98 (OJ 2000, 111), the Enlarged Board suggested that processes of genetic engineering and microbiological processes are not identical. The term microbiological processes in Art. 53(b) EPC 1973 was used as a synonym of processes using micro-organisms. Micro-organisms are different from the parts of living beings used for the genetic modification of plants. To treat genetically-modified plants as products of microbiological processes within the meaning of Art. 53(b), second part of sentence, EPC 1973, would disregard the purpose of the exclusion of plant varieties in Art. 53(b) EPC 1973, i.e. excluding from patentability subject-matter eligible for protection under the plant breeders' rights system. Therefore, the Enlarged Board took the view that it did not make any difference for the requirements under the UPOV Convention or under the Regulation on Plant Variety Rights, how a variety was obtained. Whether a plant variety was the result of traditional breeding techniques, or whether genetic engineering