

# Decision of the Administrative Council of 16 June 1999 amending the Implementing Regulations to the European Patent Convention

THE ADMINISTRATIVE COUNCIL OF THE EUROPEAN PATENT ORGANISATION,

Having regard to the European Patent Convention ("EPC"), and in particular Article 33(1)(b) thereof,

On a proposal from the President of the European Patent Office,

Having regard to the opinion of the Committee on Patent Law,

HAS DECIDED AS FOLLOWS:

## **Article 1**

1. A Chapter VI entitled "Biotechnological inventions" and containing Rules 23b, 23c, 23d and 23e as follows shall be inserted in Part II of the Implementing Regulations to the EPC.

"Chapter VI

## **Biotechnological inventions**

### *Rule 23b*

General and definitions

(1) For European patent applications and patents concerning biotechnological inventions, the relevant provisions of the Convention shall be applied and interpreted in accordance with the provisions of this chapter. Directive 98/44/EC of 6 July 1998\* on the legal protection of biotechnological inventions shall be used as a supplementary means of interpretation.

(2) "Biotechnological inventions" are inventions which concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.

(3) "Biological material" means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system.

(4) "Plant variety" means any plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a plant variety right are fully met, can be:

(a) defined by the expression of the characteristics that results from a given genotype or combination of genotypes,

(b) distinguished from any other plant grouping by the expression of at least one of the said characteristics, and

(c) considered as a unit with regard to its suitability for being propagated unchanged.

(5) A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection.

(6) "Microbiological process" means any process involving or performed upon or resulting in microbiological material.

#### *Rule 23c*

##### Patentable biotechnological inventions

Biotechnological inventions shall also be patentable if they concern:

(a) biological material which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature;

(b) plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety;

(c) a microbiological or other technical process, or a product obtained by means of such a process other than a plant or animal variety.

#### *Rule 23d*

##### Exceptions to patentability

Under Article 53(a), European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following:

(a) processes for cloning human beings;

(b) processes for modifying the germ line genetic identity of human beings;

(c) uses of human embryos for industrial or commercial purposes;

(d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

#### *Rule 23e*

##### The human body and its elements

(1) The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.

(2) An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.

(3) The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application."

2. Rule 28(6) of the Implementing Regulations to the EPC shall read as follows:

"(6) For the purposes of paragraph 3, derived biological material shall mean any material which

still exhibits those characteristics of the deposited material which are essential to carrying out the invention. The undertaking referred to in paragraph 3 shall not impede any deposit of derived biological material necessary for the purpose of patent procedure."

## **Article 2**

This decision shall enter into force on 1 September 1999.

Done at Munich, 16 June 1999

For the Administrative Council

The Chairman

*Sean FITZPATRICK*