



*Presidenza del Consiglio dei Ministri*

## **NATIONAL BIOETHICS COMMITTEE**

### **REPORT ON THE PATENTABILITY OF LIVING ORGANISMS**

(19th November 1993)

#### *abstract*

The report deals with the subject of the patentability of living organisms, excluding as a first step any discussion of the biotechnological inventions having the human body as subject, considered in its whole or in its parts. The idea in fact of patenting the human body in its entirety is considered ethically unacceptable, while the patenting of particular genes or cell lines poses a peculiar problem requiring separate attention.

The Committee takes note that the progress in molecular biology now makes it possible to modify the genetic patrimony of human beings and that the problem arises regarding the protection of the invention of genetically modified organisms. The difference in value is however highlighted existing between living and inanimate organisms and the consequences that this difference entails concerning the subject of patents. In the light of these premises, the interpretative disputes are analysed with regard to the provisions in force and the proposal of the EU directive on the protection of biological inventions presented by the Commission to the Council. According to the Committee, in a first draft the proposal in the directive did not identify the definite limits to the patenting of the living, paying excessive attention to the protection of economic interests of big companies. The second proposal analysed, which acknowledges the observations made by the European Parliament, makes considerable modifications and attempts to combine the interest for patentability to well-defined ethical principles.

The analysis of the juridical and ethical issues of the patenting of the living is carried out by distinguishing between different typologies of inventions, according to whether these have as their subject microorganisms, vegetables or superior animals. With regard to microorganisms, a recommendation is made to better define the juridical notion and to promote actions for the conservation of their biodiversity. As far as concerns the patenting of vegetables, the Committee recommends that excessively rigid solutions are not adopted, derived from the protection of other forms of invention, in order to hold back the activity of industrial biotechnology and avoid the impoverishment of the varieties grown. With regard to the patenting of superior animals, the Committee confirms its bioethical anthropocentric stance and grants the lawfulness of the experimentation and patenting of animals, providing however that well-defined limits are identified, that all procedures for the modification of genetic identity are excluded from patentability which inflict unnecessary suffering to animals, and it recommends that this kind of experimentation be for socially useful purposes.

The report includes a glossary and bibliographical references and concludes with an appendix containing the two drafts of the proposal in the EU directive on the juridical protection of biotechnological inventions, presented by the Commission to the Council.