

INTELLECTUAL PROPERTY: COMMISSION ADOPTS PROPOSAL FOR PATENTS ON BIOTECHNOLOGY INVENTIONS

Modern biotechnology inventions could soon enjoy the protection of patents and enable European biotechnology firms to compete on a sounder footing with American and Japanese companies, if the EEC Member States approve the proposal for a Directive approved by the European Commission on October 5. According to the Commission, the implementation of a harmonised system of patents is expected to encourage human and financial resource investments in research and development, promote technical innovation and facilitate the development of the EEC's biotechnology industry.

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Biotechnology is a sector which at present is enjoying tremendous growth. Inventions are being made in a wide range of sectors, such as pharmaceuticals, chemicals, food additives, energy production, environmental protection and agriculture. Statistics on patents reveal a growing increase in biotechnology patents, in particular for genetic engineering techniques. According to the Patents Office in Munich, patent applications for genetic engineering have risen 600% between 1981 and 1985. Half the requests come from the United States, Japan and approximately 25% from EEC Member States. Genetic engineering represents a potential 40 billion US Dollar market. With an annual budget of 350 million, the EEC is expected to account for a sizeable share of the world biotechnology market. Patent protection for modern biotechnology, similar to that in force in the United States and Japan, is an essential measure in this context.

Europe suffering from "patchwork" legal protection

At present, national laws in the Community are largely based on the International Convention for the Protection of New Varieties of Plants - UPOV (Paris, 1961), the Convention on the Unification of Certain Points of Substantive Law on Patents of Invention (Strasbourg, 1963), Convention on the Grant of European Patents - EPC (Munich, 1973) and the Convention for the European Patent for the Common Market (Luxembourg 1975, but not in effect). However, the conventions were drawn up at a time when biotechnological processes were either non-existent or in their infancy. The texts were never adapted, and this resulted in differing interpretations from Member States. For example, a European patent in the biotechnological field, registered at the European Patent Office in Munich, may well have its validity challenged in another Member State, because biotechnological processes or products would not be considered patentable in that Member State. This situation of legal uncertainty and a lack of sufficient protection had to be dealt with, and the Directive proposed by the Commission is meant to change all that.

Commission calls for harmonised interpretation of patent law

The Commission wants the proposed Directive to exist alongside other international conventions, such as the EPC, UPOV (of which Greece, Luxembourg and Portugal are not members) and the Treaty of Budapest. Its text must therefore be compatible with these various instruments. The EEC Directive is not aimed at implementing a Community law on industrial property for technological procedures. It is intended to provide a framework to solve certain legal problems posed by biotechnological inventions, while complying with the restrictions imposed on by the provisions and the internal right of Member States. It is expected to allow a more harmonised interpretation of European and national patents and ensure broad protection of both the various techniques of altering living organisms as well as the modified organisms themselves. The practical effects expected from the proposed Directive

The proposed Directive better defines certain fundamental legal principles regarding biotechnology inventions. It clearly states that a patent can be granted on a living organism. It also asserts that the patent law concept of discoveries does not exclude preexisting living matter from patentability, provided that a sufficient degree of human intervention has occurred. Legal protection also applies to all self-replicating inventions for the life of the patent, that is 20 years. The proposal also specifies patentability criteria for plant and animal varieties and indicates that plants and animals can benefit from a patent if the patentability conditions of novelty, invention and industrial applicability are met. The Commission

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indicates that the deposit of a micro-organism can fulfil the patent law requirement of a repeatable disclosure of the invention. Likewise, a patent granted on the basis of a deposit sample of the patented material would not be declared invalid in subsequent patent litigation for lack of sufficient disclosure of the invention.

A specific problem needs to be addressed to take account of the already existing system of plant variety protection. The Commission therefore decided not to propose product patent protection for plants where they have been produced by the use of a known biotechnological process. For patented plant material which is thereafter incorporated into plant varieties, a system of licensing between the patent rights and the breeders' rights is envisaged to ensure a beneficial dissemination of breakthroughs in modern biotechnology processes. (October 7, 1988 - European Report)(AE)

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