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A European patent law for biotechnology⁽¹⁾

Today, the Commission adopted Lord Cockfield's proposal for a draft directive to approximate national laws governing intellectual property rights for biotechnological inventions. The proposal has two main features: to enhance the legal certainty of obtaining patent protection for inventions where various forms of animate matter are concerned; and to establish the conditions for the proper functioning of the internal market in biotechnological goods.

The present position and why it needs to be improved

The present situation in the Community is that the relevant international conventions (Paris 1961; Strasbourg 1963) to which Member States are party were drawn up at a time when biotechnological processes were either non-existent or in their infancy. Adaptation of the texts of these conventions to cover these new processes and products never took place with the result that national interpretation of the conventions diverged considerably. For example, a European patent in the biotechnological field, registered at the Patent Office in Munich, may well have its validity disputed in one Member State or another, because biotechnological processes or products would not be considered patentable in that Member State. Lack of legal certainty, and lack of sufficient protection, is commonplace in the Community in this field.

Improvement is necessary both in order to introduce greater legal certainty and because of the disadvantages under which Community innovators in this field labour compared with their competitors in the US and Japan whose legislation provides considerably more protection through patentability than is currently available in Europe. The United States Patent and Trademark Office has already granted a patent on a man-made mouse from Harvard University as well as patents on plants. In Japan, several patent applications for plants and animals are expected to be granted shortly. The European Patent Office in Munich has recently given notice of its intention to grant a patent for a genetically engineered plant but hundreds of applications for plants and animals have yet to be examined.

(1) COM(88) 496

The link with the internal market

As far as the internal market is concerned, the adoption of a Community directive with the consequent minimising of the differences in legal protection for these kinds of inventions throughout the Community can be expected to induce greater intra-Community trade. Companies will be able to treat the common market as a single environment for their economic activities.

This, combined with the extra incentive offered by patentability to engage in biotechnological research, will in turn allow European industry to compete more effectively in world markets.

Content of the directive:

The directive provides answers to many of the legal questions raised by inventions in biotechnology such as:

A patent can be granted on a living organism? Answer: Yes.

How far does the patent law concept of discoveries exclude pre-existing living matter from patentability? Answer: It does not exclude it provided that a sufficient degree of human intervention has occurred.

How far do patent rights extend in patented but self-replicating inventions? Answer: In all subsequent generations for the life of the patent (20 years from date of filing).

What is the result in patent law of the exclusion of plant and animal varieties from patentability? Answer: Plants and animals are patentable if the patentability conditions of novelty, invention and industrial applicability are met.

Can a deposit of a microorganism fulfill the patent law requirement of a repeatable disclosure of the invention? Answer: Yes. Likewise a patent granted on the basis of a deposited sample of the patented material would not be declared invalid in subsequent patent litigation for lack of sufficient disclosure of the invention.

Alongside the procedural improvements envisaged by the directive, an improved system of patenting biotechnological inventions is foreseen. One of the primary goals of the directive is to 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 will be to recognise the patentability of genetically engineered products such as enhanced microorganisms, plants and animals.

Practical applications have already arisen for genetically modified microorganisms in the fields of pollution control, toxic waste treatment and microbial enhanced oil recovery. Once the directive is implemented, such microorganisms and their industrial applications will enjoy a clearer and more certain legal protection in all of the Member States of the Community and not just those few with developed patent practice and jurisprudence.

Improved plants, such as those with resistance to diseases, pests, drought, salt, pesticides and herbicides, will be patentable. New genetic material inserted into plants and animals will be considered patentable. The scope of patent rights in self-reproducing material will be defined so that the unauthorised use of such material for commercial multiplication and reproduction will fall within the patent rights. An example of this principle would be in the sale of patented barley for the production of beer: no royalties would be payable for such beer production. But if a purchaser of patented barley which was sold for the purpose of brewing beer, plants the barley and harvests a crop without authorisation, the patent rights would not be exhausted.

New patent protection and plant variety protection:

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 dispersal of the breakthroughs achieved with biotechnology.

New patent protection for animals:

Improvements in animal farming expected to benefit from the proposed directive include the genetic enhancement of breeding stock, greater control, flexibility and precision in breeding methods, prevention and control of disease, as well as the development of animals for medical and pharmaceutical research.

11