

QUESTION 82

Patent protection for biotechnological inventions

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Q82

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Patent Protection for Biotechnological Inventions

Resolution

After having considered the reports of the National Groups (Yearbook 1984/IV) and the Summary Report on Question 82 (Yearbook 1985/I),

AIPPI notes that

- an inconsistency exists between the actual laws which are based upon the general principle that a living organism *per se* cannot be the subject matter of a patent, and the state of science which nowadays makes it possible to describe and repeat procedures for the modification of a living organism
- patent protection for particular biotechnological inventions exists in most States
- processes involving the industrial use of living organisms are generally patentable
- microorganisms *per se* and other biological materials, including plants, *per se*, are patentable in many States
- plants and even animals are also protectable in some States by special rights.

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recognizes that the development of new techniques has made biotechnology of great economic importance and observes that, to encourage the development of these new techniques, there is a great desire to protect biotechnological inventions by patents and to harmonize the patent practices of different countries.

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also recognizes that the application of new techniques in biotechnology could give rise to serious moral or ethical problems, and considers that those problems should be primarily regulated by laws specifically dealing with these issues to which the patent laws of nearly all countries refer in excluding from patentability inventions contrary to morals or public order.

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is of the opinion that biotechnological inventions should be protected by the application of the existing principles of patent law and that the creation of a special body of law is not necessary. Accordingly, a subject matter in the field of biotechnology should be patentable if it meets the usual criteria for patentability.

In particular:

- there is no reason to consider an organism, be it a microorganism, plant or animal, as not being a patentable subject matter merely because it is living or merely because its genes have not been modified,
- other biological material, e.g. plasmids, enzymes, etc., should be considered patentable subject matter,
- a process for obtaining or using a living organism or other biological material, should be considered patentable subject matter,
- no reason exists to exclude from patent protection, biotechnological inventions relating to any particular field of industrial application, for example food, medicines or chemical products,
- although protection of plant varieties under laws conforming to the UPOV convention presents a valuable system of protection and should continue, it is essential that techniques newly applied and products obtained thereby in the field of the development of new plants, and capable of meeting the patentability requirements, should become generally eligible for patent protection, and therefore, prohibition of double protection should not be maintained or provided for,
- if a written description is sufficient to make the living organism, or other biological material, available to a person skilled in the art, then deposit should not be required, but nevertheless, deposit should always be considered as completing the requirement of sufficient disclosure particularly in relation to the repeatability of the invention, recognizing that practical problems in relation to some organisms will have to be solved,
- since the release of deposited material could be abused, the conclusions of AIPPI at the congresses of San Francisco and Munich in relation to microorganisms,

namely that

- a) a microorganism should not be accessible to the public until an enforceable right exists,
- b) release should be for research only,
- c) the organism should not be passed on to third parties,
- d) the organism should not be exported from the country of release and
- e) in the event of a violation of the undertaking, the burden of proof should be upon the receiver of the organism,

should be applicable to organisms, and other biological material.

- In general, there exists no reason to limit the scope of protection of patents for biotechnological inventions.

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considers that the application of these principles and the harmonization of patent practice along the lines of these principles will encourage the development of biotechnology and allow patent practice to develop in parallel with scientific advancement.

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