

## **QUESTION 114**

### **Biotechnology**

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Yearbook 1994/II, pages 396 - 397  
Executive Committee of Copenhagen, June 12 - 18, 1994

Q114

#### **Question Q114**

#### **Biotechnology**

#### **Resolution**

AIPPI

taking into account recent developments in the fields of science and law and in particular

- the Rio Convention on Biological Diversity of June 1992, establishing the principle of sovereign rights of nations over their genetic resources, and their commitment to facilitate access to those resources on mutually agreed terms; further obliging the nations to provide access for and transfer to other member countries of related technology in a parallel way; and although generally affirming the importance of intellectual property rights for technology transfer, expressly leaving room for the unfortunate interpretation that limiting intellectual property rights might better achieve its objectives;
- the GATT TRIPS Agreement of December 1993, which leaves at the disposal of Members to exclude generally from patentability not only diagnostic, therapeutic and surgical methods for the treatment of humans or animals, but also inventions in plants and animals and essentially biological processes for their production; and
- the still ongoing work of the European Union on the adoption of the Directive on the Legal Protection of Biotechnological Inventions, which reveals the questionable tendency to shift the examination of the problems of morals and ethics relating to the exploitation of biotechnological inventions from regulatory legislation to the patent offices and eventually to the Courts, and introduces special eligibility requirements for narrow types biotechnological inventions (e.g. DNA sequences with as yet known functions, i.e. Expressed Sequence Tags - EST-s);

noting that as yet no country has adopted legislation implementing the 1991 UPOV Act,

reaffirms its resolutions of Rio de Janeiro of 1985 (Q 82/Yearbook 1985 III, 312), Sydney of 1988 (Q 93/Yearbook 1988 II, 221), Lucerne of 1991 (Q 93/Yearbook 1992 II, 346) and Tokyo of 1992 (Q 93/Yearbook 1992 III, 276), and

**Resolves:**

to further study and report at the Montreal Congress on the progress of ratification and of implementation, and the impacts of the Rio Convention, the GATT TRIPS Agreement, the UPOV 1991 Act and the EU Directive on intellectual property rights of inventors active in the field of biotechnology.

(Earlier Resolutions concerning the same question respectively the same subject matter: Q82/1985 III, 312; Q93/1988 II, 221; Q93/1992 II, 346; Q93/1992 III, 276.)

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## **Question 114**

### **Biotechnology**

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Yearbook 1995/VIII, pages 375 - 377  
36th Congress of Montréal, June 25 - 30, 1995

Q114

### **Question Q114**

#### **Biotechnology**

#### **Resolution**

#### **AIPPI,**

having reviewed recent progress on ratification and implementation of the 1991 UPOV Act, of the Rio Convention on Biological Diversity of 1992, of the GATT TRIPS Agreement of 1994, including the adoption of the EU Regulation on Community Plant Variety Rights of 1994;

having also reviewed and analyzed the efforts of the European Union to adopt a Directive on the legal protection of biotechnological inventions aimed at introducing harmonized standards of protection for biotechnological inventions throughout the EU member states and the preliminary outcome thereof;

reaffirming its resolutions of Rio de Janeiro of 1985 (Q 82/Yearbook III, 312), Sydney of 1988 (Q 93/Yearbook 1988 II, 221), Lucerne of 1991 (Q 93/Yearbook 1992 II, 346), Tokyo of 1992 (Q 93/Yearbook 1992 III, 276) and Copenhagen of 1994 (Q 114/Yearbook 1994 II, 396) and in particular referring to the possible moral and ethical concerns related to inventions in biotechnology once more recalls its statement in the Sydney resolution that: "the moral or ethical problems which could arise from the application of new techniques in biotechnology should be primarily regulated by laws specifically dealing with those issues to which the patent laws of nearly all countries refer in excluding from patentability inventions contrary to morals or public order".

#### **Observes:**

1. That the UPOV Act of 1991, which fulfils most of the wishes expressed in the past AIPPI resolutions, has not yet entered into force and has been ratified only in a very small number of UPOV member states. Moreover, states who have newly joined UPOV acceded to its previous Acts only. This situation is not satisfactory and should be improved as a matter of urgency. Attention is drawn to the obligation of all WTO member states under TRIPS Art. 27 (2) (b) to provide for the protection of plant

varieties either by patents or by an effective sui generis system or by any combination thereof in all cases which meet the appropriate criteria.

2. That states which signed the Rio Convention at the present stage of ratification have not introduced any special measures in their intellectual property laws. This is to be welcomed for states the laws of which already offer an effective protection of biotechnological inventions. Since, however, effective protection of biotechnological inventions by patents and/or plant breeders' rights is instrumental for an effective transfer of technology and successful exploitation of genetic resources, such protection should be introduced in the laws of all Rio Convention signatory states. Those in charge of implementing the Rio Convention into their national laws should be well aware of the importance of intellectual property matters.
- 3.1 That the decision of the European Parliament to vote down the EU Directive on the legal protection of biotechnological inventions is to be regretted and to be viewed as cause for deep concern, notwithstanding the fact that it did not meet all the needs of inventors in the field of biotechnology and did not take into account all the wishes of AIPPI.
- 3.2 That the vote of the European Parliament may by no means affect the current practice of either the European Patent Office or of the national patent offices or courts which is firmly based on the law in force which remains unchanged.
- 3.3 That the lack of the EU Directive could eventually lead to divergent developments in legislation (as is already demonstrated by the amended French patent law of July 1994) which would likely affect legitimate interests of biotechnological inventors in the EU member states and beyond.
- 3.4 That the recent case law of the European Patent Office (T 0356/93), if upheld and followed, would deprive inventors in the field of plant and possibly also animal biotechnology of an effective protection for their generic inventions.

**Resolves:**

1. That legislative measures have to be adopted as a matter of urgency for securing the original goals of the defeated Directive as far as the subject matter eligible for patent protection and the scope of protection are concerned.
2. That any new instrument related to the protection of biotechnological inventions should observe the following principles:
  - 2.1 All biotechnological inventions including isolated genes, regardless of source, meeting the requirements of novelty, inventive step (non-obviousness) and industrial applicability (utility) should be patentable.
  - 2.2 There should be no special exceptions as to the effects of the rights protected.
  - 2.3 Exploitation of inventions is subject to compliance with general laws. Patent law should not seek to control research, development and exploitation of inventions by

restricting protectable subject matter. Value judgements as to any new technology are and should remain strictly reserved for general legislation.

- 2.4 Having regard to the special system for protecting new varieties of plants and the possible introduction of a similar system for protecting animal varieties, an adequate and effective protection of all generic inventions relating to plants and animals should be ensured.

**Expresses:**

The hope that review under Art. 27 (3) (b) GATT - TRIPS will eventually lead to the deletion of all still-allowed exclusions of patentability in the area of biotechnology, which are to be viewed as not only discriminatory but also detrimental to the progress of science and technology in this area, and which AIPPI has always opposed.

The need for AIPPI to continue to monitor closely legislative and technical developments, such as the human genome project, in this important field since they might merit the establishment of a working committee.

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## QUESTION 114

### Biotechnology

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38<sup>th</sup> Congress of Melbourne, March 23 - 30, 2001

Q114

#### Question Q114

#### Biotechnology

#### Resolution

AIPPI observes

1. that a revision of the 1978 International Convention for the Protection of New Varieties (the so-called "UPOV" Convention) was agreed upon in 1991;
2. that the aforementioned revision resulted in an important improvement of the system of protection of plant breeders rights that fundamentally differs from the system provided for in the 1978 UPOV Convention not only in terms of definition of a variety but also in terms of the scope of protection of a plant breeders right;
3. that as per January 26, 2001 the UPOV organisation has 46 member states;
4. that as per January 26, 2001 only 15 member states adhere to the 1991 UPOV Convention;
5. that therefore in a majority of the member states of UPOV the 1978 UPOV Convention is still applied;
6. that this results in major undesirable differences in the systems for protection of plant variety rights in force in the member states causing legal uncertainty;

AIPPI therefore urges those member states who still adhere to the 1978 UPOV Convention to accede to the 1991 UPOV Convention as soon as possible.

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# **Resolution**

## **Question Q114**

### **Biotechnology (including plant varieties)**

#### **on the protection of inventions regarding isolated stem cells**

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Yearbook 2005/II, page 377 – 379  
Executive Committee of Berlin, September 24 – 29, 2005

Q114

#### **AIPPI,**

##### **taking into consideration:**

- a) the achievements in various areas of technology, such as techniques for transformation and culturing of cell lines, expression, isolation and purification of proteins, the development of new and improved plant and animal varieties, including through genetic transformation of such animals as well as conventional plant and animal breeding techniques, but also in modern medicine (diagnosis and therapy) which are to a large extent based on biotechnology;
- b) the great importance of the sequencing and mapping of genomes of all organisms, including plants, animals and human beings as well as of modern technologies providing tools for an automatic decoding of gene sequences;
- c) the expectations of modern society that there will be more and more diagnostic methods and medical treatments developed on the basis of recent discoveries in the field of regenerative medicine some of which may result in recovery of previously lost body functions;
- d) that the aforementioned expectations are in a number of cases the result of discovery of the potency of adult and embryonic stem cells and therapies based on those;
- e) the need for capital and time investments to develop these discoveries into safe and reliable treatments and new and improved products and to provide means to overcome malnutrition and poor health for the individuals in need thereof.

##### **Knowing:**

- f) that modern biotechnology raises to a certain extent concerns, in particular where it concerns genetically modified organisms, especially animals, and genetically modified food;
- g) that in particular in respect of the use of human embryonic stem cells and their medical uses ethical concerns exist due to the fact that at least some stem cell types are initially recovered from human embryos that could be developed or could have developed into a whole human being;
- h) that legislation such as the EU Biotechnology Directive 98/44/EC exists giving rules to deal with those concerns;

- i) that there is no consensus across the jurisdictions as to whether research and development in the area of therapeutic cloning and the recovery of human embryonic stem cells should be permitted and that in some countries the use of cloning to produce a human embryo for the recovery of stem cells and/or the recovery of stem cells from spare embryos resulting from fertility treatment is banned while in others one or both of these activities is permitted under strict license.

**Further taking into consideration:**

- j) that the system of patent protection for new technical developments that exists around the world to stimulate and foster new technical research and development has always adapted to the challenges of new technical developments;
- k) that AIPPI at the ExCo meeting in Sydney in 1988 adopted a Resolution (Q93)
  - re-affirming the principle that inventions relating to living organisms, be they micro-organisms, plants, animals or parts thereof, or to other biological material or to processes for obtaining or using them should be patentable on the sole condition that they comply with the usual criteria of patentability and
  - expressing that the moral or ethical problems which could arise from the application of new techniques in biotechnology should be primarily regulated by laws specifically dealing with those issues, to which the patent laws of nearly all countries refer in excluding from patentability inventions "*contrary to morals or public order*";
- l) that AIPPI at the ExCo meeting in Sorrento in 2000 adopted a Resolution (Q150)
  - recognizing that ESTs, SNPs or entire genomes should be protected using the general principles of patent law and
  - recognizing that standard novelty, inventive step (non-obviousness) and sufficiency of disclosure criteria of national laws must be strictly applied to these kinds of inventions;
- m) that the TRIPS agreement requires in Art. 27 that patent protection should be available in all fields of technology;
- n) that the TRIPS agreement in Art. 27, paragraph 2 and 3 also provides for WTO Countries to introduce certain exclusions from patentability such as an exclusion in order to protect *ordre public or morality*, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law;
- o) that the patent offices of the United States, United Kingdom and Japan are granting patents in the field of human embryonic stem cell technology;
- p) that the EU Biotechnology Directive 98/44/EC provides some general rules to be applied in the assessment of the patentability of inventions in the field of biotechnology and the enforcement of patents granted in this field as well as some specific exclusions of patentability;
- q) that article 5(2) of the EU Biotechnology Directive 98/44EC confirms that elements isolated from the human body or otherwise produced by means of a technical process can constitute patentable inventions and that the specific exclusions from patentability of Article 6 do not make any reference to isolated human embryonic stem cells;
- r) that however, despite the fact that the deadline for such implementation expired in June 2000 the EU Biotechnology Directive 98/44/EC is not implemented into all national laws of all EU member states due to intense public debate on the application of modern biotechnology in general in some countries which influences the discussion of patent laws.



**Adopts the following Resolution:**

- 1) The principles adopted in the aforementioned Sydney and Sorrento Resolutions are reaffirmed;
- 2) Patents should be available without any discrimination for all kinds of inventions, including biotechnology; the prevention by countries of the exploitation or use of certain technologies should not exclude those technologies from being patented;
- 3) Inventions based on isolated human embryonic pluripotent stem cells should be treated like any other invention and should be patentable if the general patentability criteria (novelty, obviousness/ inventiveness, industrial applicability and sufficiency of disclosure) are met;
- 4) Exclusions to patentability due to the principles of *ordre public* and *morality* may be applicable but should be as limited as possible and should be defined very precisely.