Resolution

Question Q114

Biotechnology (including plant varieties)

on the protection of inventions regarding isolated stem cells

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 re–generative 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 "c*ontrary 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.