

# Patents on Life granted by EPO

## An overview of recent cases

For the occasion of the Diplomatic Conference of the European Patent Convention (EPC), to be held in Munich, 20 – 29 November 2000, Greenpeace carried out a research survey of the 'patents on life' granted in recent years by the EPO. The research covers valid patents granted on human animal chimeras, human organs and genes, animals and plant varieties. Since patent examiners were on strike for several months during this year the number of patents granted this year has been comparatively low. However the cases discussed here indicate the recent trends. Most of the patents have been granted following the decision by the EPO's Administrative Council to resume the patenting of life. (See Greenpeace paper *The Future of European Patent Law will be decided in Munich* for background to the conflict).

### 1. Patent on human-animal chimera

Despite public statements by the EPO in October 2000 that patents on mixed-species embryos would not be granted as they are considered against "public order and morality", the EPO had already granted such patents back in 1999.

For a detailed analysis of this case see Greenpeace paper on *Human-Animal Chimera Patented*.

### 2. Patents on human organs

Several patents on human organs have been granted.

- In 1994 the company Genetech (USA) was granted a patent on human organs (transplants), which had been treated with a certain growth-substance prior to the transplantation (EP 438526). The patent lists other organs including "heart, liver, spleen, pancreas, thyroid lobe, lung, kidney, intestine, blood vessel and esophagus." Specifically claimed is a "graft (transplant) ... that is derived from a human." (Claim 34)
- In May 2000 a patent was granted to Novartis (EP 669977) which covers hearts, kidneys or lungs from humans and animals. When this case made headlines in the Swiss media, Novartis publicly admitted that commercial interest were the sole reasons for the company to file this patent.

The patenting of human organs, human genes and cells are permitted under the EU-Patent-Directive (legal protection for biotechnological inventions – 98/44/EC). The patenting of human organs for transplantation operations are also permitted.

*Art. 5(2): "An element isolated from the human body or otherwise produced by means of a technical process, including the sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element."*

Even new methods to deep-freeze, propagate or transfer of human organs such as hearts and kidneys can lead to a patent covering the organ itself. When parts of the human body and organs become patented products this may lead to trade in organs and commercialisation of the human body for spare parts. As the patent holder alone can decide how, where and at which price such organ-transplants can take place, doctors' freedom to choose appropriate therapies in the interests of their patients risk being subordinated to the financial interest of the patent holder.

But the patenting of human organs also violates several national and international laws, notably the Convention on Bio-Ethics of the Council of Europe.

### 3. Patents on genes and diagnostic tests for cancer and other diseases

The negative and prohibitive cost effects of patenting genes are evident in the field of cancer research where genes play an increasingly important role in the diagnosis and treatment of cancer. These genes can have an effect on the evaluation of the course of the disease, the prospects of healing and the choice of the best therapy. But if these genes are protected by a patent then the patent holder alone can determine the use of them.

The famous example of the breast cancer gene has already shown what consequences for doctors, health authorities and patients may be expected if diagnostic methods (test kits) are controlled via patents on genes. Doctors in the United Kingdom, for example, already fear a doubling of the cost if the US company Myriad Genetics is granted patents on its applications for the two breast cancer genes BRCA1 and BRCA2. Myriad has already sold its exclusive marketing rights in the United States for treatments based on the BRCA1-gene to the company Eli Lilly & Co. Independent researchers have been denied the use of the diagnostic test kit.

The EPO has granted a number of other gene patents in the past months, which can be of importance to many more diseases:

- The US-company Millenium Pharmaceuticals was granted a patent on a gene which can be used for diagnosis and prevention of the spread of tumours (EP 817792). The company claims that this gene can deliver decisive information on the course of cancer of breast, skin, stomach and intestines, sexual organs, lungs, the pancreas and other organs;
- The John-Hopkins University (USA) now holds a patent on a gene of importance for the diagnosis of cancer of the colon (EP 580596)
- The General Hospital Corporation patented a gene which is said to control the spread of certain tumours of the nervous system (EP 613945)

In all these cases the patent not only covers certain specific applications, but rather the genes with all their functions. This even hands over control of the use of the gene in medical applications – even though the EPC explicitly prohibits the patenting of therapeutic and diagnostic methods on the human body. For example: the patent of the General Hospital Corp. even includes the sampling of patients for presence of said gene.

Patients, doctors and insurance companies are thus depending on patent holders – even though the patent law was originally designed to prevent exactly this scenario.

#### **4. Patents on plant varieties**

Since the Administrative Council of the EPO decided in June 1999 to allow patents on plants and animals, despite a clear prohibition in the EPC, as many as 10 new patents on plants, seeds and plant varieties have been granted. Many more are to be granted in the near future. Some examples for recently granted patents:

- Novartis (now Syngenta) received a patent comprising tomatoes, potatoes, tobacco, cotton, cereals, vegetables, tuber plants, fodder and turf grasses, maize, fruiting plants, oil plants, medical plants and forest trees (EP 348348);
- Zeneca (now also Syngenta) holds a patent covering all dicotyledonous plants which have been genetically manipulated with a certain method (anti-sense) (EP 532060);
- Monsanto's patent (EP 426641) covers all plants and seeds into which a certain promotor (switching-on gene) has been introduced;
- Mycogen has a patent covering maize, wheat, barley and rice (EP 459643).

These patents also cover all varieties which could ever be bred from these genetically modified plants. This means that all plant breeders, who use these plants to breed new varieties, have to pay license fees to the patent holders.

This is a clear breach of the text of the EPC. Nevertheless, these patents are valid, unless someone files oppositions. How much these patents actually target traditional breeding methods and plant varieties, is especially clear in the following patent:

- EP 465009 of Pioneer Hi-Bred (Du Pont). The patent includes wheat, rice, sorghum, maize, soy and tomatoes, the production of seeds, the cross breeding of these varieties and even the sowing of these plants. The aim of the company is to breed such varieties with the patented gene and thus gain the rights over these staple plants.

#### **5. Patents on plant breeding methods and harvests**

The agro-business is not only pursuing control over individual plants and plant varieties but also striving to gain control over the food production through the patenting of plant breeding. This is exemplified by the following cases:

The company Du Pont recently received two patents from the EPO which cover entire agricultural harvests

- EP 571500 covers the genes, the plants, seeds, methods for cross breeding and selection for the breeding of plant varieties which incorporate the patented gene, and right up to the use of the harvest as fodder;
- EP 744888 protects as an "invention" the harvesting of maize, oils derived thereof, fodder for pigs and chicken, even the act of feeding the animals, as well as the use of the oils in margarine, salad dressings and cooking oils. Du Pont does not even use genetically engineered plants. The patents covers the harvest of all maize plants the seeds of which contain a certain amount of oil. According to the patent, such varieties can also be bred by traditional breeding methods. Such plants already exist: some regional varieties have an oil-content of more than 60% in their seeds. But the claims of Du Pont start already at 50%, irrespective of how this oil-level was achieved. Thus the patent automatically covers regional varieties, such as those which have been used by farmers in South America for ages.

Through such patents countries of origin are being deprived control over their own biological diversity and this violates the Convention on Biodiversity (CBD). The EU Directive merely mentions the CBD, but does not include any legal measures to prevent this practice of biopiracy

## 6. Patented mammals

Since the Administrative Council allowed patents on plants and animals, several mammals have already been patented. Most recent example: EP 556171 grants the University of Ohio a patent on all mammals, with the exception of humans, which have been genetically manipulated with a gene for nanism (dwarf growth). Altogether there are some 500 patent applications on mammals pending.

### Greenpeace demands:

- Genes, plants, animals, humans and parts of the human body must not be patentable;
- The member states of the EPC must exercise their political control and prevent the EPO from granting further patents in these areas;
- The EU Directive on patenting biotechnological inventions should not be transposed into national law;
- The EU must initiate new European patent law, which prohibits the patenting of living organisms and their genes.