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PATENTING LIFE

The techniques of genetic modification allow useful characteristics to be introduced into living organisms, but there is debate over how far the resulting modified life forms should be patentable. US law allows patents to be considered for all modified organisms whether they be microorganisms, plants or (non-human) animals. In Europe, a Draft Directive is under consideration to allow similar rights, and is the subject of Early Day Motion (No. 755).

This briefing note considers the scientific developments which have led to the possibility of 'patenting life', and the issues raised.

'NEW' FORMS OF LIFE

Recombinant DNA technology can modify the basic genetic makeup of a living organism by inserting (or removing) sections of DNA which contain the organism's genetic instructions. Following the first successful demonstration of these techniques in 1973, their potential to introduce useful characteristics into microbes, plants and animals has been rapidly explored. Initial efforts focused on microorganisms because of the relative simplicity of their structure, and a number of commercial processes now use microorganisms which have been genetically 'programmed' to produce materials which they would not produce naturally (e.g. drugs such as human insulin, growth hormone, blood clot dissolvers; food products such as enzymes).

With plants, the intent of the traditional breeder and the genetic engineer are the same - to improve the character of a crop plant by introducing novel genetic material. The extra power of genetic engineering comes from its ability to bring new sources of genetic material to the effort of plant improvement. Genetically modified plants (see Briefing note 10) include varieties with potentially useful traits such as enhanced nutritive content, herbicide resistance and low fertiliser requirements.

Genetic modification of animals is still largely at the experimental stage. The aims of research include making meat leaner, increasing the growth rate of farm animals, and producing pharmaceutical products via farm animals' milk. The first genetically modified animal which is available for sale (by Du Pont) is a mouse which is genetically predisposed to cancer - for use in testing new drugs or chemicals for carcinogenicity.

Table 1 EXAMPLES OF PATENTS ON GENETICALLY MODIFIED LIVING ORGANISMS (US and Europe)

Granted	*Under Consideration*
● Microorganisms	
Oil-degrading bacteria	Bacteria and Viruses which act as insecticides
Genetically modified yeast	
● Plant	
Protein-enhanced forage crops	Tomatoes which don't go soft
Sunflower with enhanced oil content	Corn with increased protein
	Insect-resistant lettuce
● Animal	
Cancer-prone mouse	Animals which produce pharmaceuticals in milk
	Farm animals, fish etc with increased growth rates

The first genetic modification of human cells in a patient is currently under clinical trial in the USA. A child's bone marrow cells which were unable to produce an enzyme essential to her immune system were removed, modified to include the gene for the missing enzyme and replaced. As a result she has been able to leave the plastic 'bubble' which protected her from infections and lead a more normal life.

Insofar as these new developments have industrial utility, the industries concerned argue that they should be patentable for the same fundamental reasons that apply to other inventions. The initial applications of genetic modification raised no new issues of principle for the patenting system because the inventions could be protected by patenting the newly identified gene itself, the process of genetic modification, processes used to make the product or other means. However, some commercial applications of genetically modified organisms require that the organism itself be sold, and the question of patenting the whole organism arises. Since there are no patent statutes or treaties specific to life forms, such considerations must take place under general patent law. Examples of organism patents either granted or under consideration are in Table 1.

PATENTS

Patenting in the UK can take place either under UK patent law or, increasingly, through the European Patent Office (EPO) in Munich which affords protection in all States party to the European Patent Convention[1]. Practice in the US and Japan is also of considerable relevance to UK inventors and companies, since the US

1. The EPC is an agreement between EC States (except Denmark, Ireland and Portugal), Austria, Sweden and Switzerland to develop a European system of patents. By successfully applying through the EPO, the inventor gains patents in the EPC States of the applicant's choice.

often provides the largest single market for products developed in the UK; equally the patent protection available to a US or Japanese company in its home market affects its ability to compete in other markets.

Patent laws require that inventions demonstrate the key characteristics of novelty, inventiveness and utility. However, European and US patent laws differ in a number of respects which can be critical to the success of a patent application. For instance, the US allows a year's period of grace between an invention's publication and the deadline for a patent application. In Europe, an application is invalid if any public disclosure of the invention has already taken place[2]. Differences between the US and Europe have also emerged on the patenting of genetically modified living organisms.

With **microorganisms**, US and European patent laws allow patents on many inventions involving microorganisms - for example on useful processes (e.g. Louis Pasteur was awarded a patent for a process of fermenting beer), on formulations which include a microorganism (e.g. food yeast compositions), on methods of genetic modification, and on the genetic modification used. The EPC does not exclude the possibility of patenting a genetically modified organism *per se*, but in the USA, microbes used to be regarded as a 'product of nature' and could not be patented. This position was overturned in 1980 by the US Supreme Court which ruled that a live, human-made microorganism was patentable as a 'composition of matter'.

In the case of **plants**, a system of plant breeders' rights has evolved over many years. These are protected under the UPOV Convention (International Union for the Protection of New Varieties of Plants, 1961) which is implemented in the UK by the Plant Varieties and Seeds Act of 1964. New varieties of plants are protected by allowing only the breeder of the new variety to sell the seeds. There are however two important exemptions. Firstly, other breeders are allowed to experiment with protected varieties; secondly farmers are allowed to keep seed from the protected crop for re-sowing.

Patents on plants have evolved alongside these rights. The US has allowed certain plant patents since its Plant Patent Act of 1930, and has issued over 6,500. The Japanese have allowed plant patents since 1970. The EPC excludes "plant varieties" from patenting, but the EPO Board of Appeal recently ruled that plant patents may be awarded for useful and inventive genetic modifications - for instance a corn having an additional useful gene. The first patent issued in this category covered forage crops (such as alfalfa) with increased protein content. Over 100 other applications for plant patents are under consideration.

With **animals**, reliance has historically been placed on protection via an informal system of breeders' rights rather than patent law. While European law has excluded patenting of animal varieties up to now, US law considers since 1987 that "nonnaturally occurring nonhuman multicellular organisms, including animals", are patentable. Japan is developing guidelines for applications involving non-human animals. The first (and so far only) patent for an animal was granted by the US Patent Office to Harvard University in 1988 for a mouse which was genetically engineered to be unusually susceptible to cancer[3]. This application was initially rejected by the EPO in 1989, but is being re-examined after a review by the EPO's appeals board.

Meanwhile the European Commission has brought forward a draft directive which would facilitate the patenting of genetically modified plants and animals. This is currently before the European Parliament's Legal Affairs Committee, and is expected to be debated by the Parliament towards the end of 1991.

CURRENT ISSUES

Should Plants and Animals be Patentable?

The patenting of whole organisms, be they plant or animal, raises a number of issues which would not arise if patents were limited to specific inventive steps.

From a **legal/scientific** standpoint, there are questions over how far the requirements for a patent can be applied to whole organisms. Most such patents to date have been awarded for a plant or animal species which has been genetically modified by the insertion of one additional gene which confers the desired characteristic (Figure 1 shows steps in the genetic modification of a living organism which are relevant to patenting).

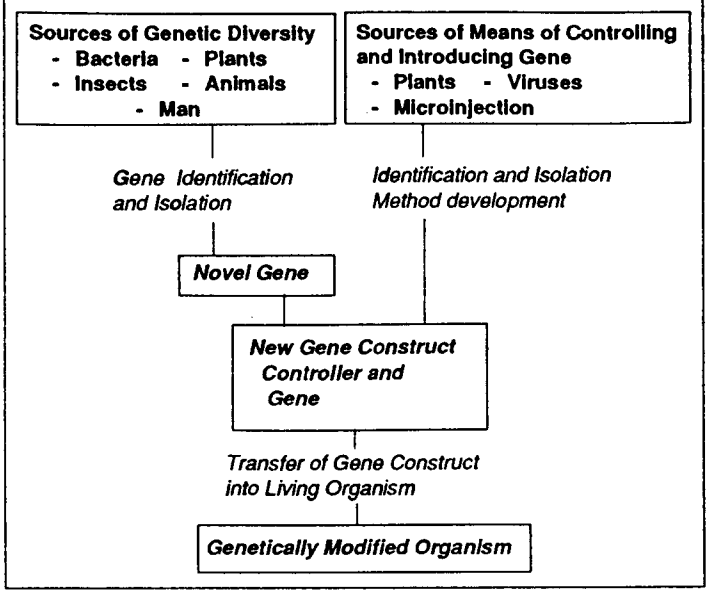
There is disagreement over how far the steps in Figure 1 comply with basic patenting criteria. Some challenge the whole principle of patenting genes and their introduction into a living organism on the grounds that:-

- the gene transferred is basically a naturally-occurring entity,
- the procedures to insert it into a plant or animal are well-known and straightforward (albeit time-consuming, tedious and expensive).

2. This rule was important for two key discoveries responsible for modern biotechnology. The first, at Stanford University in California, was of recombinant DNA techniques. This was made public in 1973, the commercial implications not having been foreseen. But within the year's grace period, press speculation on possible applications persuaded the University to apply for and gain a US patent from which substantial royalties are received. In the UK, the MRC's Laboratory of Molecular Biology was first to create hybridomas from which monoclonal antibodies are produced. Here too, the commercial potential was not foreseen, and the discovery was publicised in 1975. Under UK patent law, there was no opportunity for second thoughts, and the MRC receives no royalties from the large industry which has grown out of this technology.

3. Specifically the patent covers "a transgenic non-human eukaryotic animal (preferably a rodent such as a mouse) whose germ cells and somatic cells contain an activated oncogene sequence introduced into the animal... which increases the probability of the development of neoplasms (particularly malignant tumours) in the animal".

Figure 1 STEPS IN GENETIC MODIFICATION
(Patentable Steps in Italics)



When considering a patent for the modified organism itself, there is the further point that the modification has generally affected only one of the many genes of the organism concerned. Over 99.999% of a plant or animal's genetic makeup will remain unchanged.

These factors have already exposed differences in interpretation between US and European patent systems. Inventors have succeeded in winning US patents with very broad claims which European examiners have either refused or restricted. Critics of broad claims on living organisms believe that patenting should be restricted to specific inventive steps and not allowed to cover the whole organism. Supporters claim that without effective protection of intellectual property, research into improvements in agriculture, human health and other areas may be curtailed. They see US and Japanese laws as more adaptive and flexible to new developments in biotechnology and as conferring a competitive advantage on their biotechnology companies. The European Commission has characterised the legal framework for the protection of biotechnological inventions in Member States as unable to satisfy the needs of science or industry.

Patenting plants and animals also raises **religious and moral issues**. Patenting appears to some to represent the granting of ownership of whole life forms, and an endorsement of the anthropocentric attitude that all of nature is available for appropriation and exploitation; claiming living organisms as human inventions can also be seen as devaluing attitudes to life on which moral and ethical action is based. On the other hand, it has been argued that patenting genetically modified plants or animals raises no ethical questions which did not already exist with our historical use and genetic modification of plants and animals by traditional breeding methods.

The possible effects of patenting on **animal welfare** are also a source of potential concern. Some argue that patent protection will encourage more research into genetic modification of animals. Some modifications, though benign in intent, have led to adverse side effects (for instance inserting a growth hormone gene into pigs has the intended effect of increasing their growth rate but at the expense of making them lethargic, arthritic and susceptible to stress); suffering may thus occur. Others argue that since all such work is covered by legislation on animal experimentation, the issues raised are the general ones of the use of animals in research and farming rather than of patents.

There is also concern over how patenting (particularly of plants) squares with the issue of ownership of the **world's genetic resources**. The International Undertaking on Plant Genetic Resources of the UN Food and Agriculture Organisation (FAO) recognises genetic resources as the common heritage of humankind. The developing countries are the source of most genetic diversity, and genes from Third World crops and wild plants have been essential in increasing the productivity of major crops. Some see it as unfair for companies in the developed world to patent and therefore control the commercial use of genetic material from the Third World, without paying royalties or some form of compensation for the valuable gene(s) concerned. However, a recent conference in Oslo on sustainable use of plant genetic resources was unable to suggest specific compensatory mechanisms.

Some of the arguments above exist independently of the specific question of patenting life forms, and it has been argued that the patent system should not have to deal with such issues. Nevertheless the EPC does contain a clause allowing applications to be considered against standards of public morality, and this will be one of the considerations in the mouse and similar patent cases. Groups such as Patent Concern have called for a moratorium on patenting life to allow more time for public debate on the issue.

In the USA, the issues are being aired independently of the patent system, and various bills are under consideration in the US Congress which would introduce a moratorium on all life patents, or strengthen plant and animal breeders' rights, or make specific provision for plant and animal patenting.

Patents and Breeders' Rights

The UK has just signed a revised version of the UPOV Convention. This maintains the monopoly for the originator of a new plant variety so that no-one else is allowed to market that variety for a fixed period (generally 20 years). Breeders may continue to use the new variety in their breeding programmes, thereby retain-

ing free access to genetic material -i.e. the genetic pool is safeguarded as a public good. A further right in the original Convention - that of farmers to save and reuse seed - has been delegated to individual Governments to decide in future. The revised treaty no longer prohibits dual protection - i.e. the use of both patents and breeders' right to protect intellectual property on plants.

Patents offer the inventor greater protection than breeders' rights since the rights extend (for the lifetime of the patent) to all subsequent generations of the plant or animal which carry the patented gene. New varieties made by crossing a patented parent with another parent could be eligible for both patents and breeders' rights. Breeders see patent rights as potentially inhibiting the free exchange and use of genetic material which breeders' rights have sought to maintain. Companies claim that it is not their intention to restrict access to germ plasm, but that if a breeder subsequently markets a variety which includes the patented genetic trait (e.g. insect resistance), he should have to obtain the patent-holder's permission to market it.

Enforcing patent rights through successive generations of breeding could be difficult and some have suggested that patent rights be limited to the patented variety's initial use by the breeder, who would pay a reasonable royalty and then be free to use the patented plant or animal in subsequent breeding programmes without repetitive royalties. Companies claim however that the need to recoup investments in research and development from a single payment could make the charge prohibitive and provide a disincentive to innovation.

The current farmers' exemption to keep and reuse seed could be affected by patents. Some see an increasing requirement to pay royalties as disadvantaging the small farmer, and favouring large integrated companies with control over the whole agricultural food chain. They see a need to balance the possible loss of freedom of choice for both farmers and consumers against any economic benefits.

The EC Directive

The draft directive on the legal protection of biotechnological inventions would require Member States to apply a common set of principles and definitions to their patent laws. It requires that an invention shall not be considered unpatentable just because it is composed of living matter, and also clarifies a number of scientific and legal terms. The draft has attracted much comment and criticism from companies, public interest groups, breeders and farming interests covering the points already mentioned. There is particular disagreement over:

Patentability. Many of the steps in genetic modification are closely linked to natural processes, and there has always been room for disagreement over what is 'invention' and what is 'discovery' of a natural process. Since only 'inventions' are patentable, patent law has to differentiate between the two - generally on the basis of the amount of human intervention involved. The draft directive addresses this issue and clarifies that **any** human intervention - e.g. the simple separation of a naturally-occurring substance - renders a process or natural material potentially patentable. Some see this as making it easier to patent what may now be regarded as a discovery of a natural material rather than invention. Biotechnology companies see it as merely clarifying the applicability of patents to their industry, and point out that applications must still meet criteria of novelty and inventiveness.

Definitions. The EPC excludes 'essentially biological processes' from patenting, but does allow patenting of microorganisms. The draft directive thus seeks to classify any genetic modification of plants or animals as 'microbiological', and to restrict the use of the term 'essentially biological' to traditional breeding. Many scientists consider that these and other parts of the directive are at odds with conventional perceptions of the terms 'biological' and 'microbiological'.

Biotechnology companies thus view the draft directive as a necessary clarification to justify continued investments in research, as necessary for the commercial success of biotechnology, and important to the Community's future industrial development. Opponents see it as relaxing the requirements for patenting and enabling what are essentially natural organisms and processes to become the monopoly of the patentee, after conceptually simple work. They believe that the patent system is ill-suited to dealing with living organisms and biological processes, and argue that patent law should be re-examined to bring it up to date with current biotechnological capabilities.

The EC has also issued a draft regulation on breeders' rights within the Community. This has some inconsistencies with the biotechnology patents directive, but some believe that it offers an approach which is better suited to protecting the intellectual property of living organisms. Others see it as important to develop both systems in parallel, so that different approaches can be used depending on whether modern or traditional techniques of genetic modification are involved.

FURTHER READING

Additional details and background information are available from POST, 2 Little Smith St., London SW1P 3DL, tel: (071)-222-2688.

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