

Susan Watts asks whose life it is anyway

Patents Pending

When scientists invent something, whether a wristwatch telephone or a solar-powered bicycle, it is generally accepted that they will apply for a patent as a way of protecting their rights over the invention. But one of the youngest of technologies, genetic engineering, has prompted a fierce debate over the established principles of intellectual property. Should plants and animals with altered genes be considered 'inventions' and thus be patentable? In other words, should we patent life?

The question has already polarised opinions, yet most of the British public knows little about the true capabilities of the science involved. But over the next few months we should all be hearing a lot more about patents and life, since the European Parliament is about to consider a draft law that would allow patents on plants and animals with modified genes.

'Opponents fear the patenting of human beings. Human cells, cultured in the laboratory, have already been patented as tools for producing useful enzymes and drugs'

One engineered animal has already satisfied the patent authorities in the United States. In 1988, Harvard University granted a patent on the 'Oncomouse', a tailor-made mouse with extra 'oncogenes' that make it susceptible to cancer. The chemicals company Du Pont now has a licence to sell the mouse to anyone interested in cancer research.

The mouse patent has had a harder time in Europe than in the US, partly because of the broadness of Harvard's claims. The appeals board of the European Patent Office has told its examiners to consider whether the altered mouse offends public morality - a legal twist used in the past to prohibit patents on contraceptives. This has sounded alarm bells in patent offices everywhere - the board has brought into the debate all the thorny

moral and ethical issues patent examiners would rather avoid.

At present, plants and animals are not patentable, since they are products of nature rather than inventions. But the new law classes engineered organisms as 'not essentially biological' - and therefore as patentable. The staggering advances of molecular biology and the development of reliable genetic engineering techniques since the mid-1970s have produced many animals and plants that would not exist if it were not for their 'inventors': the genetic engineers who extracted and manipulated the extra genes that make them special.

Many such 'products' now wait in the wings, ready to enter the marketplace. They include pigs with extra growth hormone genes that make them fatten faster; rabbits with genes altered so that they produce drugs in their milk, as living factories; tomatoes engineered to stay firm; and staple food crops equipped with genetic material that makes them store more protein, or renders them resistant to pests and viruses.

The proposed European legislation has motivated a broad coalition of interested parties to come together to oppose it. Patent Concern includes more than 30 animal welfare, religious, legal, farming and environmental organisations: groups such as Greenpeace, the Genetics Forum, the RSPCA and Christian Aid. They have expressed their anxieties in open letters to prime minister John Major, and president of the European Commission Jacques Delors.

The Patent Concern coalition believes that the planned law could have damaging social and economic consequences. They also believe that the possibility of monopoly ownership on living things raises ethical questions about people's relationship with the rest of nature. They argue that such concerns outweigh the need to encourage an emerging biotechnology industry, even if it does have the potential to



bring substantial wealth to many of Europe's member states.

Religious opponents of the law argue that to claim to 'patent' life is a direct denial of God as creator and sustainer. Others are anxious about animal welfare issues, as a new industry develops and scientists push animals' bodies to their physiological limits. Pigs with extra growth hormone genes, and rabbits used as 'bio-reactors' to produce drugs in their milk, have been born infertile, with crippling disabilities and poor vision.

The Patent Concern coalition also says that to grant such patents could drastically increase the control of a few large companies over agriculture and genetic resources, particularly in developing countries. At the moment farmers can re-sow seed or breed from farm animals as they wish, and

many communities depend on the genetic diversity of their native plants to develop new crops and drugs. But crops engineered by biotechnologists are often based on DNA taken from species found in the developing world. In the future, farmers could find themselves buying engineered seeds, built by biotechnology companies using DNA extracted from those same plants. They might have to pay hefty royalties to companies who hold patent rights over every seed from a genetically engineered crop and every piglet from an altered pig.

If control over the food supply were to slip into the hands of a few large biotechnology or chemical companies, then consumers would face the risk of higher prices and less choice, according to the new coalition. They argue that handing control of the world's genetic res-



ources to industry in this way would raise the chances of ecological problems, such as the threat of famine when highly specialised crops are wiped out by disease.

Patents would also hinder the free flow of scientific information, the coalition argues. Chemical companies which support university researchers might discourage them from publishing papers in the scientific journals, because this would amount to a disclosure and risk sacrificing the company's chance of gaining patents.

The biotechnology industry is sympathetic to some of these concerns, but maintains that the new technology requires substantial initial investment, despite the fact that it holds the promise of lucrative new markets. Investors may pull out if companies cannot assure them that they will be able to secure patents.

Many of the developments should prove beneficial to society as a whole, the industry argues, helping to protect the environment by reducing the need for pesticides and producing abundant supplies of more nutritious crops. Granting licences to farmers, breeders and researchers who want to use its patented plants and animals is the industry's preferred route for recouping some of its costs. They maintain that without royalties from licensees on new crops, farmers will find themselves paying higher prices to cover the cost of research.

They also say that patenting the work of researchers is the best way to ensure that information reaches the public domain, since a company cannot gain a patent without describing the work in sufficient detail to enable a practising genetic engineer to repeat the work.

Momentum in Europe for allowing patents on plants and animals is gathering force. The pressure is on in part because of a huge international scientific project to work out the sequence of the DNA that makes up a human: the Human Genome Project. Scientists will apply for patents on the potentially useful stretches of human DNA they decipher, especially those with clinical applications such as the chance to develop pre-natal probes to detect genetic disorders.

But opponents of the proposed European law fear that this technological march will trip unchecked into the patenting of human beings, raising the spectre of fetuses with genetic material designed and owned by their parents. Human cells, cultured in the laboratory, have already been patented as tools for producing useful enzymes and drugs.

Last summer John Moore, a sufferer from hairy-cell leukaemia, was found to have unusual cells in his spleen, capable of producing a protein that could help scientists better understand cancer. The University of California has patented Moore's cells, and two companies, Genetics Institute in Massachusetts, and Sandoz Pharmaceutical in New Jersey, intend to develop drugs from the cells. Moore appealed for a share in the profits from his spleen, but was turned down by the State Supreme Court of California. Researchers and the biotechnology industry breathed a sigh of relief: they will depend increasingly on cells such as Moore's in developing future drugs.

Both the US and European patent offices have said they do not intend the industry to allow patents on human beings. But lawyers working on the new legislation have yet to agree on wording that will outline the delicate distinction between human cells and human beings. This delay has increased the opposition's anxiety at a time when research in areas such as gene therapy is progressing apace, holding up a real chance for parents to rid their offspring of genetic defects.

The legal battle over the proposed European law will centre on the interpretation of the word 'variety'. Plants and animals that fall into the 'varieties' clause of the European Patent Convention are not patentable. But if a 'variety' is defined only as a plant or animal produced by traditional breeding practices, genetically engineered plants and animals will be excluded - and will therefore be patentable.

The time has come for the debate to broaden out beyond the legal niceties of patent law. What people must decide, and let their MPs know, is whether an inventor should be denied a patent on a plant or animal that results from much painstaking research simply because the product is alive. Is there anything intrinsically different about life that should stop us exploiting it?