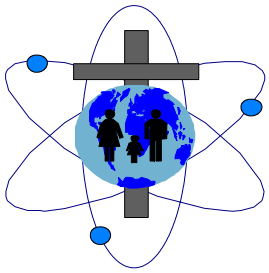
SOCIETY, RELIGION AND TECHNOLOGY PROJECT

Church of Scotland



SHOULD WE PATENT GENES?

Who should own the rights to genes, stem cells and transgenic organisms?

One of the hottest controversies in genetics concerns patenting genes and living organisms. We can map the human genome and modify organisms, but who owns the rights to their use? According to an EU Directive passed in 1998 almost anything biological must now be patentable, in order to ensure future medical discoveries and maintain a competitive biotechnology industry. Many religious and environmental groups see this as unacceptable, reducing nature to a mere commodity, and imposing the agenda of industry over the ethical values of ordinary people. Who's right?

What's the Church doing here?

The Society, Religion and Technology Project (SRT) of the Church of Scotland has been prominent in the debate over biotechnology patenting at national and international levels and in the media. SRT examined the issues in its 5 year working group study "Engineering Genesis" (Earthscan, 1999) on the ethics of genetic engineering in animals and plants. It also works closely with the bioethics working group of the Conference of European Churches, engaging with the European institutions during the Patent Directive negotiations and subsequent developmemts. This information sheet lays out the main issues and outlines the Church of Scotland's official position from its General Assembly in May 1997.

What is a Patent and Why is it Important?

A patent is granted to someone who invents something novel which has an industrial use. Its purpose is to prevent other people from marketing it without paying royalties to the inventor. It lasts 20 years to allow a fair return on the inventor's investment, on condition that the full details are published. It does not give the inventor the right to *make* the invention (that is subject to other regulations) but it can stop others doing so. It must be something novel, not an obvious extension of present knowledge, and you cannot patent a mere discovery. It has to have a practical use. The patent system has evolved over centuries around products of industry like mechanical inventions or chemical processes.

Up to about 1980, products of nature were normally excluded. You couldn't patent a plant, say. But once biotechnology began to discover ways of modifying living organisms, first bacteria and then plants and animals, pressure mounted to allow patents on these. Genetic research is expensive and it often takes years from discovery to market. In a competitive world, companies say they have a legitimate need to know they have a chance to protect their large research investment with a patent. The question is how far should this be taken? The EU Directive has aroused widespread criticism that it has bowed to the demands of industry to the point that basic public values were simply overridden.

Should we allow patents on living organisms?

To get a patent you have to have invented something. Under European law, you can't claim a patent on something merely discovered in nature. Can humans claim to have invented a genetically modified animal or plant, just because they have added one or two genes to it? For the church this would make an unwarranted claim to have invented a creature which is part of God's creation, or which is a product of nature. To extend the scope of patenting from industrial artifacts and processes to living things *in themselves* is to violate a normal ethical distinction between what is alive and what is not. Animals and plants are not just another industrial commodity. Christian moral principles stress the idea of relationship and care for nature as more important than a purely functional view of industrial utility.

The relationship with life takes precedence over commercial utility. So you may justifably patent a mouse trap, but not a genetically modified mouse. What has been invented is merely a new gene sequence used with the mouse - and that may indeed be patentable - but not the mouse itself.

Should we allow patents on human genes and human stem cells?

Equally controversial is patenting the knowledge of human genetic sequences or stem cells. The church considers it unacceptable to claim invention over genes, as they are part of our human make up. Patents are not allowed on human body parts, so why patent genes or cells? This is not "patenting life" but these are key aspects of our human make up. Moreover, in a normal understanding genes are discoveries, and should be unpatentable. However, the stakes are high to allow gene patenting. One company claimed that human DNA should be patentable because the intellectual effort to discover it raises it from a discovery to an invention. Such special pleading abuses the idea of patenting. Since all discoveries require intellectual effort, this would end the notion of discovery altogether. According to the EU directive, human genes become a patentable invention for a different reason. Genes have to copied millions of times in order to be analysed. The EU says these 'copy genes' are inventions. Quite apart from ethical objections, there is widespread doubt about the validity of this logic. Some scientists point out that the act of copying genes is not novel, but a standard technique. Others note that the key thing is the *information* encoded in the gene, which remains unchanged. By definition this ranks as a discovery. The EU has been deaf to such concerns, however, because the copy gene argument provided a convenient device to compete with more lax patent legislation in the USA.

Gene and Stem Cell Patents may create undesirable monopolies

Patenting genetic discoveries also implies a worrying attitude of "winner takes all" over knowledge which could address areas of great human suffering. It has led to undignified races to stake claims of commercial priority over genes. At times the acclaimed mapping of the human genome has seemed more like the Wild West. Patenting also does not *always* encourage the spread of medical research or investment. Sometimes it may block research or add to the cost of therapies. Investment in medical research could be ensured adequately by allowing patents on an application of a human gene to make specified therapeutic products, without patenting the gene itself or any other uses it may have. Similar concerns exist over human stem cell lines and replacement cells derived from them. Again, such cells are discoveries and not inventions. In that cells of the human body are common heritage of all people, to grant cell patents would violate ethical norms. It would be contrary to the public good to give any one organisation a broad monopoly over potential ways to treat a wide range of otherwise incurable human diseases. It might also compromise equitable access to therapies. Over both genes and stem cells, companies need to be called to account by society for what they do with any monopoly rights they are given. These vital areas must not be allowed to be a gold rush merely driven by commerce.

How do we decide what is ethical in biotechnology?

Some say ethics has no place in patenting. Yet every activity involving law also involves ethics. The EC's official advisors on bioethics have said that once animate matter is involved, ethics becomes a prominent issue in patenting. This raises a serious question about how our society should assess the progress of biotechnology. Often the first time the public hear about a biotechnological invention is when the patent is published. Until then it is secret. Objections can be raised, but the patent process is not the best place to debate and decide about bioethics. Patent lawyers are not trained in ethics and cannot speak for society. And because a patent gives no right to market the invention, it isn't (at least in theory) a judgement about ethics, either way. The problem is that no proper system exists, either in Europe or the UK, which allows for an ethical assessment to be made of a biotechnological invention, while its patent is being assessed, to enable society to decide whether it wants it to be marketed or not. This serious deficiency urgently needs to be addressed, if this vital area of science is to remain accountable to the public, directed for the common good, not driven by commercial interests alone.

For details of our book "Engineering Genesis" or about these and other ethical issues in technology, contact :
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PATINF2.LWP
Revised 9/9/02