

Patent

A patent gives an inventor the right for a limited period to stop others from making, using or selling an invention without the permission of the inventor. It is a deal between an inventor and the state in which the inventor is allowed a short-term monopoly in return for allowing the invention to be made public. Patents are about functional and technical aspects of products and processes.

Most patents

are for incremental improvements in known technology—evolution rather than revolution.

The technology does not have to be complex.

- Specific conditions must be fulfilled to get a patent. Major ones are that the invention must be new. The invention must not form part of the “state of the art”. The state of the art is everything that has been made available to the public before the date of applying for the patent. This includes published documents and articles, but can also include use, display, spoken description, or any other way in which information is made available to the public.
- Involve an inventive step, as well as being new, the invention must not be obvious from the state of the art. Obviousness is from the viewpoint of a person skilled in the area of technology that the invention is in.
- Be industrially applicable. This condition requires that the invention can be made or used in any kind of industry.

A patented invention is recorded in a patent document. A patent document must have

- description of the invention, possibly with drawings, with enough details for a person skilled in the area of technology to perform the invention.
- claims to define the scope of the protection. The description is taken into account while interpreting the claims.

The original patent document of a patent application is published by a patent office. The application then adds to the state of the art for later applications and anyone can comment on the application. Often the patent document needs altering or amending to meet the conditions above before a patent can be granted. The final version of the granted patent document is then republished. If more information about the state of the art is discovered after grant, the patent document can be amended and republished again.

Patent rights are territorial; a UK patent does not give rights outside of the UK. Patent rights last for up to 20 years in the UK. Some patents, such as those for medicinal products, may be eligible for a further 5 years protection with a Supplementary Protection Certificate.

A patent can be of value to an inventor—as well as protecting his business, patents can be bought, sold, mortgaged, or licenced to others. They also benefit people other than the inventor since large amounts of information can be learnt from other peoples patents — they can stop you from reinventing things or you can monitor what your competitors are doing. Patents also spur you or others on to develop your idea further, and once the term of the patent expires it can be freely performed by anyone which benefits the public and the economy.

There are three types of patents:

1. Utility Patents may be granted to anyone who invents or discovers any new and useful process, machine, article of manufacture, or composition of matter, or any new and useful improvement thereof;

2. Design Patents may be granted to anyone who invents a new, original, and ornamental design for an article of manufacture; and

3. Plant Patents may be granted to anyone who invents or discovers and asexually reproduces any distinct and new variety of plant.

Four Main Issues of Patents in Biotechnology

(a) What is a patent, and why is it so important in biotechnology?

(b) Should we allow patents on living organisms and human genes?

(c) When does a discovery become a human invention?

(d) How do we decide what is ethical in biotechnology?

(a) 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 stops 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.

(b) Should we allow patents on living organisms?

To get a patent you have to have invented something. Can humans claim to have invented a genetically modified animal or plant, just because they have added one or two genes to it? What have we really invented is not the animal but the new sequence. Underlying this is an important insight. To extend patenting from industrial artefacts to living things in themselves is to violate a normal ethical distinction between what is alive and what is not. They are not just another industrial commodity. The relationship with life takes precedence. So we may patent a mouse trap, or a novel gene sequence used in a mouse, but not a genetically modified mouse itself, and so also for other animals and plants.

(c) Should we allow patents on human genes?

One of the hottest issue is whether we might patent the knowledge of a human genetic sequence. In normal understanding this is a discovery, and so should be unpatentable. Patents are not allowed on human body parts, so why patent genes, which are just as much part of our human make up? But according to the EU patent directive, even a human gene becomes a patentable invention because you have to copy it millions of times in order to analyse it, so the resulting "copy genes" are inventions. Quite apart from the ethical objections, many scientists dispute the logic of this, because the key thing is the

information encoded in the gene. By definition that is a discovery. Also the act of gene copying is not novel but a standard technique.

(d) When does a discovery become a human invention?

One company has claimed that human DNA is patentable because the intellectual effort to discover it raises it from a discovery to an invention. To many, this is a case of special pleading which would abuse the very idea of patenting, since *all* discoveries require intellectual effort. Logically, this would bring an end to the notion of discovery and mean that anything could become a commodity.

(e) 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.

Often the first time the public hear about a biotechnological invention is when the patent is published. Up to this point, it is secret. 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 in the world, 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 and not driven by commercial interests alone.