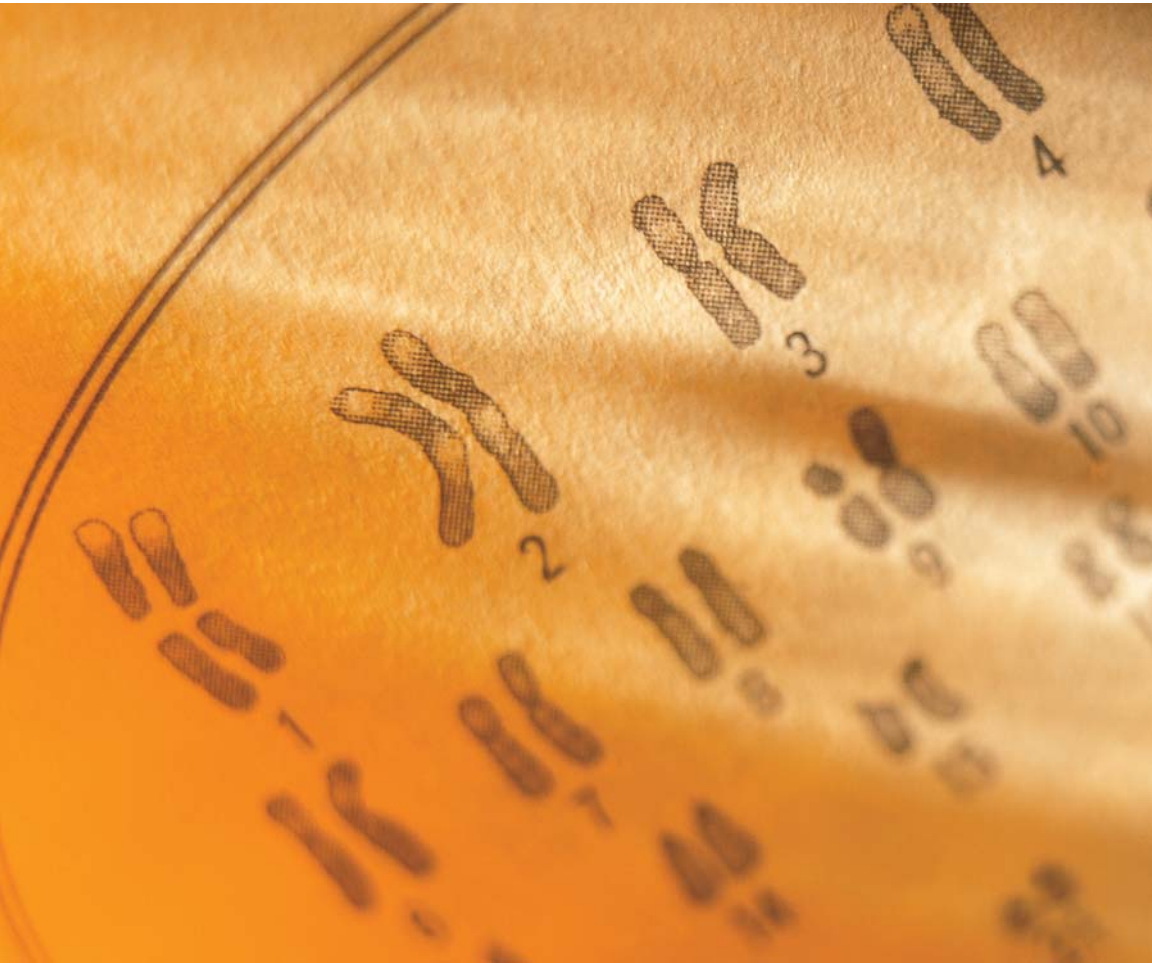


Gene Patenting

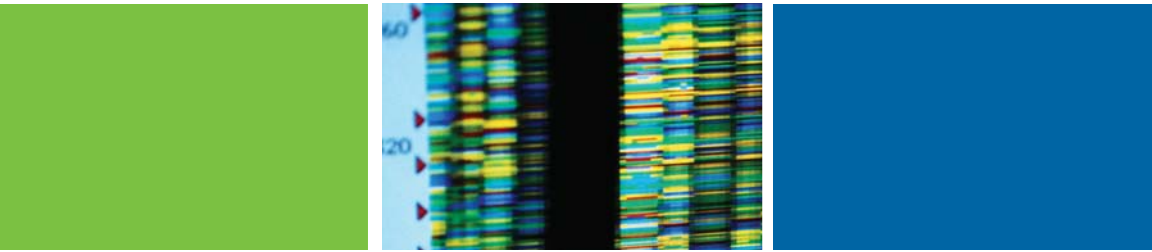


Life form means a living thing. A life form can be anything from a virus or a plant to a human being.

Gene Patenting



Patenting genetic materials is a complex issue. Both the public and scientists are concerned about it. Their concerns center around two things: the patenting of life forms and creating barriers to research. Roche hopes this booklet will address some of these concerns. The booklet answers some questions about gene patenting and explains Roche's position.

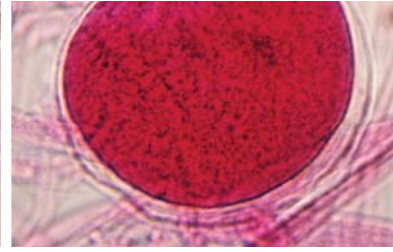


Why do we have a patent system?

It takes a long time and a lot of hard work to invent something and to prove it works. Once you have done that, it's easy for someone else to copy your invention. The patent system was set up to protect the inventor's work and investment. It also encourages inventors to invent for the benefit of all people. Patenting does this by giving people the incentive to invest in research and development of new products and processes. It also encourages more research by others. This is because patenting includes publishing detailed information about the invention that may help others in their own research.

What is a patent?

A patent is an exclusive, but temporary right granted to an inventor or to their successors. It prevents others from exploiting the invention unless they have the patent owner's consent. Exploiting an invention includes making, using, selling, or importing it. Patents provide protection only for a limited time (normally 20 years). The patent owner also can let others use it. For example, he or she can grant a license for an appropriate fee.



Novel means new or not identical.

Non-obvious means that a knowledgeable scientist in this field would not easily see this invention or application. In other words, a skilled person would conclude that the differences between the invention and what was known previously are not immediately evident.

How does one get a patent?

To get a patent, an inventor must have more than just an idea. He or she must have made an actual invention and be able to describe it. With this description, a skilled person should be able to make and use the invention, if allowed to do so. Inventions can only be patented if they are novel and non-obvious and useful in a real-world sense. Also, the patent application must describe the invention in enough detail for a person skilled in the field to reproduce it.

Example: If you invent a new way to catch a mouse, you can patent your mousetrap design. But if you take someone else's mousetrap design and just make it bigger, you can't patent it as a "rat trap" because it would be obvious to change the size.

On the other hand, very small differences or improvements sometimes can result in enormous and unexpected advantages and may be patentable. For example, the addition of one carbon atom to poisonous wood alcohol (methanol) creates liquor (ethanol).

What is the difference between an invention and a discovery?

An invention is a process or a product that can be described in writing in such a way that a skilled person is able to reproduce what has been described. Based on the description, a skilled person must be able to obtain the same result every time. The process or product, in turn, must be novel, based on an inventive activity, and be useful in a real world sense. On the other hand, a discovery is the mere finding of something new, which was unknown or unrecognized before. Roche believes that discoveries should not be patentable.

Discovery Becomes Invention — An Example

Aspirin is used in treating pain, heart disease and stroke. Aspirin is made from a compound found in willow bark and was known to the ancient Greeks. Scientists were able to patent aspirin in 1899 after they found a way to synthesize it and package it.

Does holding a patent give a patent owner the right to use, make, sell, or import his or her patented invention?

No. Having a patent doesn't mean the patent owner can make or sell his/her invention. It just means that no one else can. Often, an inventor needs other government approvals to use his or her invention. In particular, in the pharmaceutical industry, it is necessary to get approval from certain agencies before marketing a drug. These agencies include the FDA (Food and Drug Administration) in the United States and/or the central regulatory body in the European Union, the European Agency for the Evaluation of Medicinal Products or EMEA. A patent owner may also need licenses from other patent owners before he or she can make use of this invention. This is the case if there is an overlap of patent rights. For example, a single patent may not cover all the aspects of a complex technology.

*When Is More Than One Patent Needed? —
An Example of Basic v. Improvement Inventions*

Before the modern doorknob was invented, a doorknob was just a handle to push or pull a door open or shut. Suppose you were the person who invented the doorknob that could turn and latch the door when closed. You could have patented that invention. Anyone who used a doorknob that turns and latches would need your permission. Now suppose another person took your doorknob invention and added a lock and key mechanism to it. That person would have to get your consent to use your doorknob invention before he or she could make and sell locking doorknobs. The person also could get an improvement patent on the lock and key mechanism.

Why are patents so important to biomedical research?

Pharmaceutical, diagnostics, and biotechnology companies must invest very large sums of money to develop new products. The research tends to be difficult and costly. The risks are enormous and researchers often fail many times before having a new, successful product. Companies can only make and justify these investments if patent protection lets them get their money back and a return on their investments.

What is Roche's stand on patent protection for genetic materials?

Roche supports granting patent protection for genetic materials. (Genetic materials include DNA, genes, and gene sequences.) The patent application should meet the same high standards that apply to other inventions, according to a country's laws. This means the genetic invention must be novel, non-obvious and useful. Its function and use in healthcare must be fully described as well.

Does this mean that a specific gene or gene sequence of a human being can be patented?

They can be patented only if further work is done to change the gene. In other words, an inventive step is needed to make it unobvious. Such extra work may include isolating, purifying, and identifying the gene or gene sequence. Plus, all the other general requirements for getting a patent must also be met. (Also see the above answer on patents and genetic materials.)

Does this mean that a human being’s genome can be owned by someone else?

No. Patents cannot give ownership of a person’s genome. However, patents may be granted on specific, isolated genes and gene products that result from research using human tissue samples. But such patents must fulfill all the other requirements for getting a patent. Moreover, researchers must have the informed consent of any individuals giving samples.

Isolated genes and gene products refer to molecular entities that can be further processed in a practical way and not to the genetic information contained in these genes, gene variants, or gene products.



Some people say that gene patents keep other researchers from doing more research on the patented invention and, therefore, hinder access to healthcare. Is that true?

They could. Patents, however, should not be permitted to bar basic research on a patented invention. In fact, the information published with a patent should be used to advance new technology. This actually stimulates more research and inventions. Other inventors can thereby continue the scientific progress begun by an invention. To address people's concerns, Roche supports a research exemption that encourages further innovation. Scientific research aimed at gaining new knowledge related to the subject of a patented invention must be accessible.

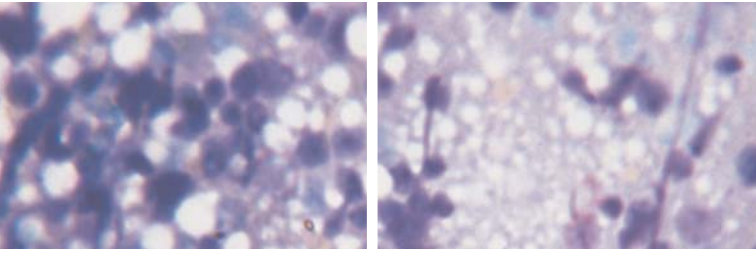
Is it possible to abuse the patent system by tying up basic genetic information so that other researchers can't use it?

In theory, it might be. Most often, however, it is in a patent owner's interest that others use his or her invention. Roche supports reasonable licensing programs for research tools to promote research, innovation, and medical progress. Roche supports a legislated right to a license to use patented inventions in the laboratory for pure research purposes. Such a right would guard against potential abuses of patent rights.

Does the law allow the following and what is Roche's stand on these issues?

- *patents on the cloning of human beings?*
- *germ line modification of human beings?*

Roche supports laws such as the European Directive on the patenting of biotechnological inventions. The European Directive forbids any patents on the cloning of human beings and germ line modification of human beings.



Cloning is copying cells from a single cell in the laboratory.

Germ line modification is changing the egg or sperm so that a genetic change is carried on to future generations.

Does Roche support the idea that stem cells and stem cell lines are patentable?

No. However, stem cells and stem cell lines that have been modified through an inventive process should be patentable. They also must be fully described and shown to be novel, non-obvious, and useful. (Stem cells are cells that can develop into more than one kind of cell. A stem cell line refers to a population of uniform stem cells from a single source.)

Finally, what is Roche's stand on patenting life forms?

Roche opposes the patenting of the human body and its parts. Roche also supports current restrictions on patenting animal and plant varieties. However, micro-organisms and genetically-modified plants and animals should be patentable.



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