What are patents, and how do they work?

The patentability of inventions under U.S. law is determined by the Patent and Trademark Office (USPTO) in the Department of Commerce. A patent application is judged on four criteria. The invention must be "useful" in a practical sense (the inventor must identify some useful purpose for it), "novel" (i.e., not known or used before the filing), and "nonobvious" (i.e., not an improvement easily made by someone trained in the relevant area). The invention also must be described in sufficient detail to enable one skilled in the field to use it for the stated purpose (sometimes called the "enablement" criterion).

In general, raw products of nature are not patentable. DNA products usually become patentable when they have been isolated, purified, or modified to produce a unique form not found in nature.

The USPTO has 3 years to issue a patent. In Europe, the timeframe is 18 months. The USPTO is adopting a similar system. Patents are good for 20 years from filing date.

In the United States, patent priority is based on the "first to invent" principle: whoever made the invention first (and can prove it) is awarded property rights for the 20-year period. Inventors have a one-year grace period to file after they publish. All other countries except the Philippines, however, follow a "first inventor to file" rule in establishing priority when granting patents.

Many biotech patents have been applied for as provisional patents. This means that persons or companies filing the provisional patent application have up to one year to file their actual patent claim. The provisional patent must contain a written description of said invention and the names of the inventors. This one-
year grace period does not count as one of the 20 years that the patent is issued for.

When a biotechnology patent involving an altered product of nature is issued, the patent holder is required to deposit a sample of the new invention into one of the 26 worldwide culture depositories. Most DNA-related patents are issued by the USPTO, the European Patent Office, or the Japanese Patent Office.

Currently over three million genome-related patent applications have been filed. U.S. patent applications are confidential until a patent is issued, so determining which sequences are the subject of patent applications is impossible. Those who use sequences from public databases today risk facing a future injunction if those sequences turn out to be patented by a private company on the basis of previously filed patent applications.

### Patenting Genes, Gene Fragments, SNPS, Gene Tests, Proteins, and Stem Cells

**In terms of genetics**, inventors must
1. identify novel genetic sequences,
2. specify the sequence's product,
3. specify how the product functions in nature -- ie, its use
4. enable one skilled in the field to use the sequence for its stated purpose

**Genes and Gene Fragments**

USPTO has issued a few patents for gene fragments. Full sequence and function are often not known for gene fragments. On pending applications, their utility has been identified by such vague definitions as providing scientific probes to help find a gene or another EST or to help map a chromosome. Questions have arisen over the issue of when, from discovery to development into useful products, exclusive right to genes could be claimed.

The 300- to 500-base gene fragments, called expressed sequence tags (ESTs), represent only 10 to 30% of the average cDNA, and the genomic genes are often 10 to 20 times larger than the cDNA. A cDNA molecule is a laboratory-made version of a gene that contains only its information-rich (exon) regions; these molecules provide a way for genome researchers to fast-forward through the genome to biologically important areas. The original chromosomal locations and biological functions of the full genes identified by ESTs are unknown in most cases.

Patent applications for such gene fragments have sparked controversy among scientists, many of whom have urged the USPTO not to grant broad patents in this early stage of human genome research to applicants who have neither characterized the genes nor determined their functions and uses.

In December 1999, the USPTO issued stiffer interim guidelines (made final in January 2001) stating that more usefulness—specifically how the product functions in nature—must now be shown before gene fragments are considered patentable. The new rules call for "specific and substantial utility that is credible," but some still feel the rules are too lax.

The patenting of gene fragments is controversial. Some say that patenting such
discoveries is inappropriate because the effort to find any given EST is small compared with the work of isolating and characterizing a gene and gene product, finding out what it does, and developing a commercial product. They feel that allowing holders of such "gatekeeper" patents to exercise undue control over the commercial fruits of genome research would be unfair. Similarly, allowing multiple patents on different parts of the same genome sequence --say on a gene fragment, the gene, and the protein-- adds undue costs to the researcher who wants to examine the sequence. Not only does the researcher have to pay each patent holder via licensing for the opportunity to study the sequence, he also has to pay his own staff to research the different patents and determine which are applicable to the area of the genome he wants to study.

SNPs
Single nucleotide polymorphisms (SNPs) are DNA sequence variations that occur when a single nucleotide (A,T,C,or G) in the genome sequence is altered. For example a SNP might change the DNA sequence AAGGCTAA to ATGGCTAA. SNPs occur every 100 to 1000 bases along the 3-billion-base human genome. SNPs can occur in both coding (gene) and noncoding regions of the genome. Many SNPs have no effect on cell function, but scientists believe others could predispose people to disease or influence their response to a drug.

Variations in DNA sequence can have a major impact on how humans respond to disease; environmental insults such as bacteria, viruses, toxins, and chemicals; and drugs and other therapies. This makes SNPs of great value for biomedical research and for developing pharmaceutical products or medical diagnostics. Scientists believe SNP maps will help them identify the multiple genes associated with such complex diseases as cancer, diabetes, vascular disease, and some forms of mental illness. These associations are difficult to establish with conventional gene-hunting methods because a single altered gene may make only a small contribution to the disease.

In April 1999, ten large pharmaceutical companies and the U.K. Wellcome Trust philanthropy announced the establishment of a non-profit foundation to find and map 300,000 common SNPs (they found 1.8 million). Their goal was to generate a widely accepted, high-quality, extensive, publicly available map using SNPs as markers evenly distributed throughout the human genome. The consortium planned to patent all the SNPs found but to enforce the patents only to prevent others from patenting the same information. Information found by the consortium is freely available.

Gene Tests
As disease genes are found, complementary gene tests are developed to screen for the gene in humans who suspect they may be at risk for developing the disease. These tests are usually patented and licensed by the owners of the disease gene patent. Royalties are due the patent holder each time the tests are administered, and only licensed entities can conduct the tests.

Proteins
Proteins do the work of the cell. A complete set of genetic information is contained in each cell. This information provides a specific set of instructions to the body. The body carries out these instructions via proteins. Genes encode proteins.

All living organisms are composed largely of proteins, which have three main
cellular functions: to provide cell structure and be involved in cell signaling and cell communication functions. Enzymes are proteins.

Proteins are important to researchers because they are the links between genes and pharmaceutical development. They indicate which genes are expressed or are being used. Important for understanding gene function, proteins also have unique shapes or structures. Understanding these structures and how potential pharmaceuticals will bind to them is a key element in drug design.

Stem Cells
Therapeutic cloning, also called "embryo cloning" or "cloning for biomedical research," is the production of human embryos for use in research. The goal of this process is not to create cloned human beings but rather to harvest stem cells that can be used to study human development and treat disease. Stem cells are important to biomedical researchers because they can be used to generate virtually any type of specialized cell in the human body. See the Cloning page for more information on therapeutic and other types of cloning.

Cell lines and genetically modified single-cell organisms are considered patentable material. One of the earliest cases involving the patentability of single-cell organisms was Diamond v. Chakrabarty in 1980, in which the Supreme Court ruled that genetically modified bacteria were patentable.

Patents for stem cells from monkeys and other organisms already have been issued. Therefore, based on past court rulings, human embryonic stem cells are technically patentable. A lot of social and legal controversy has developed in response to the potential patentability of human stem cells. A major concern is that patents for human stem cells and human cloning techniques violate the principle against the ownership of human beings. In the U.S. patent system, patents are granted based on existing technical patent criteria. Ethical concerns have not influenced this process in the past, but, the stem cell debate may change this. It will be interesting to see how patent law regarding stem cell research will play out.(1)

Why patent?
Research scientists who work in public institutions often are troubled by the concept of intellectual property because their norms tell them that science will advance more rapidly if researchers enjoy free access to knowledge. By contrast, the law of intellectual property rests on an assumption that, without exclusive rights, no one will be willing to invest in research and development (R&D).

Patenting provides a strategy for protecting inventions without secrecy. A patent grants the right to exclude others from making, using, and selling the invention for a limited term, 20 years from application filing date in most of the world. To get a patent, an inventor must disclose the invention fully so as to enable others to make and use it. Within the realm of industrial research, the patent system promotes more disclosure than would occur if secrecy were the only means of excluding competitors. This is less clear in the case of public-sector research, which typically is published with or without patent protection.

The argument for patenting public-sector inventions is a variation on the standard
The argument is that postinvention development costs typically far exceed preinvention research outlays, and firms are unwilling to make this substantial investment without protection from competition. Patents thus facilitate transfer of technology to the private sector by providing exclusive rights to preserve the profit incentives of innovating firms. Patents are generally considered to be very positive. In the case of genetic patenting, it is the scope and number of claims that has generated controversy.

What are some of the potential arguments for gene patenting?

- Researchers are rewarded for their discoveries and can use monies gained from patenting to further their research
- The investment of resources is encouraged by providing a monopoly to the inventor and prohibiting competitors from making, using, or selling the invention without a license.
- Wasteful duplication of effort is prevented.
- Research is forced into new, unexplored areas.
- Secrecy is reduced and all researchers are ensured access to the new invention.

What are some of the potential arguments against gene patenting?

- Patents of partial and uncharacterized cDNA sequences will reward those who make routine discoveries but penalize those who determine biological function or application (inappropriate reward given to the easiest step in the process).
- Patents could impede the development of diagnostics and therapeutics by third parties because of the costs associated with using patented research data.
- Patent stacking (allowing a single genomic sequence to be patented in several ways such as an EST, a gene, and a SNP) may discourage product development because of high royalty costs owed to all patent owners of that sequence; these are costs that will likely be passed on to the consumer.
- Because patent applications remain secret until granted, companies may work on developing a product only to find that new patents have been granted along the way, with unexpected licensing costs and possible infringement penalties.
- Costs increase not only for paying for patent licensing but also for determining what patents apply and who has rights to downstream products.
- Patent holders are being allowed to patent a part of nature --a basic
constituent of life; this allows one organism to own all or part of another organism.

- Private biotechs who own certain patents can monopolize certain gene test markets.
- Patent filings are replacing journal articles as places for public disclosure -- reducing the body of knowledge in the literature.

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**What does U.S. patent policy say about gene patenting?**

- **1980 Diamond v. Chakrabarty**
  Prior to 1980, life forms were considered a part of nature and were not patentable. Diamond v. Chakrabarty changed this with the 5 to 4 U.S. Supreme Court decision that genetically engineered (modified) bacteria were patentable because they did not occur naturally in nature. In this case, Chakrabarty had modified a bacteria to create an oil-dissolving bioengineered microbe.

- Since Diamond v. Chakrabarty, patents have been issued on whole genes whose function is known. More recently, inventors began to seek patents on sequences of DNA that were less than a whole gene. The Patent Office has developed guidelines on how to deal with these fragments since they often do not have a known function.

- Some patents have been granted for fragments of DNA. That presents the problem of someone trying to patent a larger fragment or gene that contains the already patented sequence. Questions have been raised as to whether the second inventor will need to obtain a license from the first or whether he can obtain the patent without the first patent holder's permission. These types of questions are likely to arise in the near future and will most likely be resolved in courts designated to hear patent actions.

- Patents have been prohibited by Congress in only a few cases where the issuance of a patent was contrary to the public interest. An example of this was the prohibition of patents on nuclear weapons. The American Medical Association has made a similar request against the patenting of medical and surgical procedures.


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**How does genome information placed in the public domain work? Who can use it?**

All genome sequence generated by the Human Genome Project has been deposited into GenBank, a public database freely accessible by anyone with a connection to the Internet. For an introduction on how to search GenBank and other nucleotide databases at the National Center of Biotechnology Information, see the [Gene and Protein Database Guide](http://www.ornl.gov/sci/techresources/Human_Genome/elsi/patents.shtml) and a related tutorial available at [Gene](http://www.ornl.gov/sci/techresources/Human_Genome/elsi/patents.shtml).
Gateway, an online guide to learning about genes, proteins, and disorders.

Disseminating information in the public domain encourages widespread use of information, minimizes transaction costs, and makes R&D cheaper and faster. Of particular relevance to research science, a vigorous public domain can supply a meeting place for people, information, and ideas that might not find each other in the course of more organized, licensed encounters. Information in the public domain is accessible to users who otherwise would be priced out of the market.

Related Links

Patent and Intellectual Property Organizations


General Patent Information

- [How Patents Work](http://www.howstuffworks.com) - From the Howstuffworks Web site.  

Gene Patenting

Government Resources


Web Sites

- [Gene Patenting](http://www.americanmedicalassociation.org) - From the American Medical Association.  
- [A Primer on Gene Patents](http://www.americanmedicalassociation.org) --From the American Medical Student Association, 2001.  
- [Biotechnology and Gene Patents](http://www.consumerproject.org) - Collection of gene patent information from the Consumer Project on Technology.
Statements and Position Papers


Educator Resources

- To Own or Not to Own DNA - Two lessons targeted to high school students from actionbioscience.org, March 2002.

Articles and Reports

- Gene Patents Inhibit Innovation - From New Scientist, July 23, 2002
- Genome Scientists: Gene Patents are Bad - From Forbes, June 2002.
- Gene Patents May Stunt Research - From News in Science, an Australian news service, November 11, 2002.
- DNA Patents Create Monopolies on Living Organisms - Actionbioscience.org article from the Council for Responsible Genetics, April 2000.

References

Information on this page was compiled from numerous sources including but not limited to HUGO, *Science, The Scientist, Gene Letter, Signals* Magazine, and *Human Genome News*.

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