Connecticut Debate Association
March 6, 2010: Darien School and Glastonbury High School
Resolved: The patenting of human DNA should not be permitted.

Courts Consider Who Owns the Human Genome

by Jane Bosveld; Discover: Science, Technology and the Future

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Myriad Genetics owns the patent over certain breast cancer genes, effectively giving them ownership over any test involving the genes.

When Lisbeth Ceriani, a 43-year-old Massachusetts woman, was diagnosed with breast cancer last year, her doctors recommended that she undergo genetic testing to see if she carried mutations in the *BRCA1* and *BRCA2* genes that increase risk of breast and ovarian cancers. She had several risk factors for inherited cancer, including relatives who had died from breast and ovarian cancer. "My dad's mother wasn't diagnosed with ovarian cancer, but we feel sure she had it after reviewing her symptoms," Ceriani says.

When Ceriani's doctors submitted her blood to Myriad Genetics—the only company that offers a sequencing test for *BRCA* mutations—the company refused to process it, saying that Myriad did not accept Ceriani's health insurance. She could not afford to pay for the test herself (it costs nearly $4,000), so she did not have it done. If there had been a cheaper test or a company that took her insurance, she would have known quickly what her best treatment options were.

There is only one test for *BRCA* mutations because Myriad controls the *BRCA* genes. The U.S. Patent and Trademark Office awarded the company its first patent in 1997; by 2000 the patent office had awarded it eight more, in effect giving Myriad ownership of the genes. Accordingly, the company is allowed to decide who may study the genes and has written cease-and-desist letters to university geneticists working on alternative *BRCA* sequencing tests.

This year Myriad's patent was challenged in court by the American Civil Liberties Union on behalf of 20 plaintiffs, including the American College of Medical Genetics, the Association for Molecular Pathology, and various individuals, including Ceriani. The lawsuit charges that the *BRCA* patents—and gene patents in general—violate established laws that prohibit the patenting of products and laws of nature. According to the ACLU, "Human genes, even when removed from the body, are still products of nature."

Critics also argue that the process of locating specific genes does not warrant the awarding of patents. "A number of researchers had been looking for the genes related to breast cancer and knew where the genes were likely to be," says Arupa Ganguly, a geneticist at the Hospital of the University of Pennsylvania and one of the plaintiffs in the ACLU suit. "Essentially the work was done for Myriad already. Everyone knew where the gene was." Myriad has refused to comment and in July filed a motion to dismiss the lawsuit. That motion was denied by a New York federal district court in November.

Robert Cook-Deegan, director of the Institute for Genome Sciences and Policy at Duke University, does credit Myriad with discovering specific mutation sequences and building a public database of genetic variations—both valuable contributions. But he says that many scientists believe Myriad's control has slowed or blocked research, and it "certainly has made researchers more cautious in how they report relevant findings." At the least, geneticists in the United States do not have the option of making a more accurate screening test because doing so would infringe on Myriad's patent.

The ACLU argues that gene patents as a whole inhibit the free flow of ideas and should not be awarded. "Gene patents defy common sense," says Chris Hansen, one of the ACLU lawyers handling the case. "If you're at a cocktail party and you tell people human genes are patented, almost everyone will say that can't be right."

Right or not, about 20 percent of all human genes already have been included in patent claims. Whether that number will stand or even grow will depend on how the ACLU suit is decided.

Human Genome Project (http://www.ornl.gov/sci/techresources/Human_Genome/elsi/patents.shtml)

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 often are 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 justification for patents in commercial settings. 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.

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.

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 and a related tutorial available at Gene 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.

In Defense of Gene Patenting

The Principles of Our Patent System Are Sound and Bring Immense Benefits

Geoffrey M. Karny; Genetic Engineering and Biotechnology News, April 7, 2007

(Geoffrey M. Karny is a partner in the Washington, D.C., office of Baker & Daniels, a law firm)

Gene patenting has been under attack for several years. Various academics have been leading the charge, closely followed by groups that perceive their professional interests to be threatened.

Now science fiction novelist Michael Crichton has jumped on the bandwagon. In his book Next, Crichton brings forth a host of biotech bad guys who represent virtually every stereotype imaginable. They include a greedy venture capitalist, dishonest and hypocritical scientists, a body-part-selling pathologist, and the obligatory sleazy lawyer.

Gene patenting is one of several biotech hot-button issues that run through the novel. In fact, Crichton even included an appendix in which he argues against gene patenting. It is the usual suspects—nobody should own our genes because they exist in nature, and gene patents are bad public policy because they suppress research and hurt patient care.

One is tempted to dismiss the novel, hoping that its poor reviews will limit the number of readers and, therefore, the dissemination of misinformation.

Unfortunately, the biotech industry cannot be complacent. Congressmen Xavier Becerra (D-Calif.) and David Weldon (R-Fla.) introduced a bill (H.R.977) to prospectively ban gene patents. The key provision states, “Notwithstanding any other provision of law, no patent may be obtained for a nucleotide sequence, or its functions or correlations, or the naturally occurring products it specifies.” Congressman Becerra’s introductory remarks make many of the same arguments that Crichton does.

Therefore, it is necessary to review, once again, the reasons why patents on genes are proper under U.S. patent law and why they represent wise social policy.

Foundation of the Industry

Gene patents, more specifically patent claims to nucleotide sequences, such as genes, plasmids, and probes, are fundamental and critical to the biotech industry. They are the foundation of the industry. Such claims protect

therapeutic proteins, like human insulin; Mabs, like Herceptin®; transgenic plants, like insect-resistant corn; and diagnostic probes for genetic diseases, which are the foundation for personalized medicine. Banning such patents risks shutting down a large part of the industry and creating a major roadblock to progress in patient care and food production.

Inventions do not move from the laboratory to the marketplace without a huge investment of money, time, and effort. A Tufts University study has found that it takes over $800 million to bring a new drug to market. The author is not aware of similar studies for transgenic plants or gene-based diagnostics, but the cost must be substantial, even if less than for drugs.

For diagnostics in particular, critics have argued that it is a relatively quick and straightforward process for a laboratory to develop a molecular diagnostic once a particular disease-associated gene has been identified in the scientific literature. However, an examination of financial disclosure documents of some molecular diagnostic companies indicate that this is not the case.

For example, the prospectus for **Genomic Health's** IPO, dated September 8, 2005, states that the company would use $20 million of the proceeds to fund R&D. **Third Wave's** 10-K for 2005, the latest available, states that it spent $8.4 million for R&D for that year. These amounts would cover several products, but clearly a substantial amount of money is involved. Quite simply, this investment will not happen if, after it is done, a competitor can get a free ride on the pioneer's efforts and knock-off the product.

Basic (but overlooked) Patent Law Principles and Policies

The Constitution provides for patents. The founders recognized that it takes time, money, and effort to develop an invention to the point where it can benefit humankind. Thus, they authorized Congress to provide inventors with the right to exclude others from the invention for a limited period of time. Thus, a patent is a limited property right. It is not a reward. It is also not a monopoly, even though the right extends to a class of things, because a monopoly is defined by market power. As many a disappointed inventor well knows, having a patent is no guarantee of commercial success. Quite simply, a patent is granted to provide the inventor and/or his company or investors the incentive to undertake the costly and risky process of further development and commercialization. They will do so because they can charge enough for the product to recover their investment.

In return, the public gets the invention, but not for free. What it gets for free is the new technical knowledge to build on because the patent must disclose how to make and how to use the invention in terms that a person skilled in that technology can understand. And, after the patent expires, the public even gets the invention for free.

The public is protected because the patent statute permits no more than the actual contribution made by the inventor to be the subject of the limited property right. The invention must be novel, that is, not disclosed in any printed document found anywhere in the world or publicly known or used in the U.S. Thus, the law recognizes the basic fact that the inventor created something that did not exist before. The invention must be useful. The invention must not be obvious; that is, the novelty should not be a trivial one that any person of routine skill in the technology could have envisioned. The invention must be described in a manner to enable other people skilled in that technology to make and use it. This permits others in the field to build on the new knowledge. Finally, the invention must be clearly claimed so that the public knows the scope of the limited property right.

How Can Someone Patent a Gene?

Crichton and other critics often ask, "How can anyone own my genes?" The answer is that they cannot. What someone can "own" is a DNA sequence that he or she was the first to isolate and that is useful. Similarly, a person who discovers a new function of a known DNA sequence, such as its previously unknown association with particular disease, can patent a method of using the isolated sequence to detect susceptibility to that disease. Isolated DNA sequences do not occur in nature. They are new.

Claiming them as isolated sequences is not "mere word play" as asserted by Congressman Becerra in his remarks. Rather, the language reflects the critical fact that, but for the actions of the inventor, the invention would not exist. The gene for human Factor VIII doesn't do a hemophiliac any good when it is in somebody else's genome. It is only useful when someone isolates it and a company spends time and money to bring human Factor VIII to the market. Since isolated DNA sequences do not occur in nature, they are not natural products. By patenting them, the inventor takes nothing from the public.

Social Policy: Myth v. Reality

The critics say that gene patents are bad social policy—they hinder research, raise costs, and limit patient access to care.

Academic researchers believe that scientific advancement occurs through the publication of research results. Society agrees that research is valuable and encourages it through billions of dollars of taxpayer-funded grants. However, this culture of information-sharing and government grants appears to have created a culture of entitlement where the property rights of others, specifically patent rights, are expected to be freely available in the name of research.

As with any human activity, even one as important as scientific research, there have to be limits. Respecting the patent rights of others has to be one of those limits if society is going to gain the benefits of the patent system.

As a practical matter, however, academic scientists who ignore patent rights have little to fear. The vast majority of patent owners simply do not want the adverse publicity of suing scientists and their universities, and the economic recovery is seldom worth the effort and money spent. They want patents in order to exclude competitors, trade them for needed technology, or raise money from investors.

The often-cited case of Madey v. Duke University (307 F.3d 1351 (Fed. Cir. 2002)), where a former Duke University professor sued the university for infringement of patents that he owned, is an aberration. The university had forced Madey out of his position as a laboratory director, and he responded with a powerful weapon that he had at hand—a patent-infringement suit.

More importantly, the fact that Duke was found to have infringed his patents goes to a fundamental aspect of the patent law. The law recognizes a limited research exemption from infringement. This exemption is limited to an examination of the patented invention; that is, research on the invention. This is completely consistent with the policy underlying the patent law of encouraging others to build upon the knowledge disclosed in the patent, including developing improvements or "inventing around" the patent.

This is quite different from using the patented invention in research. Simply because an organization is a nonprofit entity and/or engaged in a noble enterprise like scientific research does not mean that the organization or its employees have the right to infringe the patents of others. A patented reagent may cost more, but that is simply a cost of engaging in the activity, like any other cost.

Critics have also charged that patents raise costs to patients and/or limit patient access to medical care. One cited study is Cho et al., J. Mol. Diagn., 5: 3-8 (2003). The article reports the results of a telephone survey of 211 directors of laboratories that do molecular diagnostic testing. Of 122 respondents, 25% reported discontinuing performing patented genetic tests, and 53% stated they did not develop new tests because of patents.

However, a closer examination of the article shows that the respondents simply did not want to pay to license the patented tests. One of the respondents even acknowledged this by stating, "People shouldn't be complaining that they can't run tests. They should just pay." Access to patented technology is a cost of doing business. Facilities and reagents are not free, and employees do not work for free. Why should new technology be free? The tests are available. It's just a question of cost.

We Need Gene Patents

In the noise and misinformation about gene patents, basic, common-sense principles are lost. These principles have supported the patent system for over 200 years and have contributed to the technological greatness of this nation and to the benefits that technology brings to humankind. They bear repeating. The inventor brings something new to the world. The patent provides the incentive to bring it to market. And new biomedical and agricultural products improve the human condition.

Crichton and the other antigene patent folks love to talk about mouse traps. They have no problem with patenting better mouse traps. But society will have a problem if they get their way. We will have plenty of mouse traps but far fewer new drugs and diagnostics and far less food.

OP-ED CONTRIBUTOR: Patenting Life

By MICHAEL CRICHTON

The New York Times, February 13, 2007

(Michael Crichton is a writer and filmmaker, and has an MD from Harvard Medical School.)

YOU, or someone you love, may die because of a gene patent that should never have been granted in the first place. Sound far-fetched? Unfortunately, it's only too real.

Gene patents are now used to halt research, prevent medical testing and keep vital information from you and your doctor. Gene patents slow the pace of medical advance on deadly diseases. And they raise costs exorbitantly: a test for breast cancer that could be done for $1,000 now costs $3,000.

Why? Because the holder of the gene patent can charge whatever he wants, and does. Couldn't somebody make a cheaper test? Sure, but the patent holder blocks any competitor's test. He owns the gene. Nobody else can test for it. In fact, you can't even donate your own breast cancer gene to another scientist without permission. The gene may exist in your body, but it's now private property.

This bizarre situation has come to pass because of a mistake by an underfinanced and understaffed government agency. The United States Patent Office misinterpreted previous Supreme Court rulings and some years ago began — to the surprise of everyone, including scientists decoding the genome — to issue patents on genes.

Humans share mostly the same genes. The same genes are found in other animals as well. Our genetic makeup represents the common heritage of all life on earth. You can't patent snow, eagles or gravity, and you shouldn't be able to patent genes, either. Yet by now one-fifth of the genes in your body are privately owned.

The results have been disastrous. Ordinarily, we imagine patents promote innovation, but that's because most patents are granted for human inventions. Genes aren't human inventions, they are features of the natural world. As a result these patents can be used to block innovation, and hurt patient care.

For example, Canavan disease is an inherited disorder that affects children starting at 3 months; they cannot crawl or walk, they suffer seizures and eventually become paralyzed and die by adolescence. Formerly there was no test to tell parents if they were at risk. Families enduring the heartbreak of caring for these children engaged a researcher to identify the gene and produce a test. Canavan families around the world donated tissue and money to help this cause.

When the gene was identified in 1993, the families got the commitment of a New York hospital to offer a free test to anyone who wanted it. But the researcher's employer, Miami Children's Hospital Research Institute, patented the gene and refused to allow any health care provider to offer the test without paying a royalty. The parents did not believe genes should be patented and so did not put their names on the patent. Consequently, they had no control over the outcome.

In addition, a gene's owner can in some instances also own the mutations of that gene, and these mutations can be markers for disease. Countries that don't have gene patents actually offer better gene testing than we do, because when multiple labs are allowed to do testing, more mutations are discovered, leading to higher-quality tests.

Apologists for gene patents argue that the issue is a tempest in a teapot, that patent licenses are readily available at minimal cost. That's simply untrue. The owner of the genome for Hepatitis C is paid millions by researchers to study this disease. Not surprisingly, many other researchers choose to study something less expensive.

But forget the costs: why should people or companies own a disease in the first place? They didn't invent it. Yet today, more than 20 human pathogens are privately owned, including haemophilus influenza and Hepatitis C. And we've already mentioned that tests for the BRCA genes for breast cancer cost $3,000. Oh, one more thing: if you undergo the test, the company that owns the patent on the gene can keep your tissue and do research on it without asking your permission. Don't like it? Too bad.

The plain truth is that gene patents aren't benign and never will be. When SARS was spreading across the globe, medical researchers hesitated to study it — because of patent concerns. There is no clearer indication that gene patents block innovation, inhibit research and put us all at risk.

Even your doctor can't get relevant information. An asthma medication only works in certain patients. Yet its manufacturer has squelched efforts by others to develop genetic tests that would determine on whom it will and will not work. Such commercial considerations interfere with a great dream. For years we've been promised the coming era of personalized medicine — medicine suited to our particular body makeup. Gene patents destroy that dream.

Fortunately, two congressmen want to make the full benefit of the decoded genome available to us all. Last Friday, Xavier Becerra, a Democrat of California, and Dave Weldon, a Republican of Florida, sponsored the Genomic Research and Accessibility Act, to ban the practice of patenting genes found in nature. Mr. Becerra has been careful to say the bill does not hamper invention, but rather promotes it. He's right. This bill will fuel innovation, and return our common genetic heritage to us. It deserves our support.

Patents, from Wikipedia, the free encyclopedia

Law

A patent is not a right to practice or use the invention.[13] Rather, a patent provides the right to exclude others[13] from making, using, selling, offering for sale, or importing the patented invention for the term of the patent, which is usually 20 years from the filing date [3] subject to the payment of maintenance fees. A patent is, in effect, a limited property right that the government offers to inventors in exchange for their agreement to share the details of their

inventions with the public. Like any other property right, it may be sold, licensed, mortgaged, assigned or transferred, given away, or simply abandoned.

A patent being an exclusionary right does not, however, necessarily give the owner of the patent the right to exploit the patent.[13] For example, many inventions are improvements of prior inventions that may still be covered by someone else's patent.[13] If an inventor takes an existing, patented mouse trap design, adds a new feature to make an improved mouse trap, and obtains a patent on the improvement, he or she can only legally build his or her improved mouse trap with permission from the patent holder of the original mouse trap, assuming the original patent is still in force. On the other hand, the owner of the improved mouse trap can exclude the original patent owner from using the improvement.

Some countries have "working provisions" that require the invention be exploited in the jurisdiction it covers. Consequences of not working an invention vary from one country to another, ranging from revocation of the patent rights to the awarding of a compulsory license awarded by the courts to a party wishing to exploit a patented invention. The patentee has the opportunity to challenge the revocation or license, but is usually required to provide evidence that the reasonable requirements of the public have been met by the working of invention.

Enforcement

Patents can generally only be enforced through civil lawsuits (for example, for a U.S. patent, by an action for patent infringement in a United States federal court), although some countries (such as France and Austria) have criminal penalties for wanton infringement.[14] Typically, the patent owner will seek monetary compensation for past infringement, and will seek an injunction prohibiting the defendant from engaging in future acts of infringement. To prove infringement, the patent owner must establish that the accused infringer practices all the requirements of at least one of the claims of the patent…

An important limitation on the ability of a patent owner to successfully assert the patent in civil litigation is the accused infringer's right to challenge the validity of that patent. Civil courts hearing patent cases can and often do declare patents not valid...

The vast majority of patent rights, however, are not determined through litigation, but are resolved privately through patent licensing. Patent licensing agreements are effectively contracts in which the patent owner (the licensor) agrees to forgo their right to sue the licensee for infringement of the licensor's patent rights, usually in return for a royalty or other compensation. It is common for companies engaged in complex technical fields to enter into dozens of license agreements associated with the production of a single product. Moreover, it is equally common for competitors in such fields to license patents to each other under cross-licensing agreements in order to share the benefits of using each other's patented inventions.

Ownership

In most countries, both natural persons and corporate entities may apply for a patent. In the United States, however, only the inventor(s) may apply for a patent although it may be assigned to a corporate entity subsequently[15] and inventors may be required to assign inventions to their employers under a contract of employment.

The inventors, their successors or their assignees become the proprietors of the patent when and if it is granted. If a patent is granted to more than one proprietor, the laws of the country in question and any agreement between the proprietors may affect the extent to which each proprietor can exploit the patent. For example, in some countries, each proprietor may freely license or assign their rights in the patent to another person while the law in other countries prohibits such actions without the permission of the other proprietor(s).

The ability to assign ownership rights increases the liquidity of a patent as property. Inventors can obtain patents and then sell them to third parties.[17] The third parties then own the patents and have the same rights to prevent others from exploiting the claimed inventions, as if they had originally made the inventions themselves.

Rationale

There are four primary incentives embodied in the patent system: to invent in the first place; to disclose the invention once made; to invest the sums necessary to experiment, produce and market the invention; and to design around and improve upon earlier patents.[22]

1. Patents provide incentives for economically efficient research and development (R&D). Many large modern corporations have annual R&D budgets of hundreds of millions or even billions of dollars. Without patents, R&D spending would be significantly less or eliminated altogether, limiting the possibility of technological advances or breakthroughs. Corporations would be much more conservative about the R&D investments they made, as third

parties would be free to exploit any developments. This second justification is closely related to the basic ideas underlying traditional property rights.[22][specify]

2. In accordance with the original definition of the term "patent," patents facilitate and encourage disclosure of innovations into the public domain for the common good. If inventors did not have the legal protection of patents, in many cases, they would prefer or tend to keep their inventions secret. Awarding patents generally makes the details of new technology publicly available, for exploitation by anyone after the patent expires, or for further improvement by other inventors. Furthermore, when a patent's term has expired, the public record ensures that the patentee's idea is not lost to humanity.[22][specify]

3. In many industries (especially those with high fixed costs and either low marginal costs or low reverse engineering costs — computer processors, software, and pharmaceuticals for example), once an invention exists, the cost of commercialization (testing, tooling up a factory, developing a market, etc.) is far more than the initial conception cost. (For example, the internal "rule of thumb" at several computer companies in the 1980s was that post-R&D costs were 7-to-1). Unless there is some way to prevent copies from competing at the marginal cost of production, companies will not make that productization investment.[22][not in citation given]

One effect of modern patent usage is that a small-time inventor can use the exclusive right status to become a licensor. This allows the inventor to accumulate capital from licensing the invention and may allow innovation to occur because he or she may choose to not manage a manufacturing buildup for the invention. Thus the inventor's time and energy can be spent on pure innovation, allowing others to concentrate on manufacturability.[23]

Criticism

Patents have been criticized for being granted on already-known inventions. In 1938, R. Buckminster Fuller wrote of the patent application process in the United States:[26]

At present, the files, are so extraordinarily complex and the items so multitudinous that a veritable army of governmental servants is required to attend them and sort them into some order of distinguishable categories to which reference may be made when corresponding with patent applicants for the purposes of examiner citation of "prior art" disclosure. This complexity makes it inevitable that the human-equation involved in government servants relative to carelessness or mechanical limitations should occasion the granting of multitudes of "probably" invalid patent claims.

Patents have also been criticized for conferring a negative right upon a patent owner, permitting them to exclude competitors from using or exploiting the invention, even if the competitor subsequently develops the same invention independently. This may be subsequent to the date of invention, or to the priority date, depending upon the relevant patent law (see First to file and first to invent).[27]

Patents may hinder innovation as well in the case of "troll" entities. A holding company, pejoratively known as a "patent troll", owns a portfolio of patents, and sues others for infringement of these patents while doing little to develop the technology itself.[28] Other commentators suggest that patent trolls are not bad for the patent system at all but instead realign market participant incentives, make patents more liquid, and clear the patent market.[29]

Another theoretical problem with patent rights was proposed by law professors Michael Heller and Rebecca Sue Eisenberg. Based on Heller's theory of the tragedy of the anticommons, the authors argued that intellectual property rights may become so fragmented that, effectively, no one can take advantage of them as to do so would require an agreement between the owners of all of the fragments.[30]

Pharmaceutical patents prevent generic alternatives to enter the market until the patents expire, and thus maintains high prices for medication.[31] This can have significant effects in the developing world, as those who are most in need of basic essential medicines are unable to afford such high priced pharmaceuticals.[32] Critics also question the rationale that exclusive patent rights and the resulting high prices are required for pharmaceutical companies to recoup the large investments needed for research and development.[31] One study concluded that marketing expenditures for new drugs often doubled the amount that was allocated for research and development.[33]

In one response to these criticisms, one review concluded that less than 5 percent of medicines on the World Health Organization's list of essential drugs are under patent.[34] Also, the pharmaceutical industry has contributed US$2 billion for healthcare in developing countries, providing HIV/AIDS drugs at lower cost or even free of charge in certain countries, and has used differential pricing and parallel imports to provide medication to the poor.[34] Other groups are investigating how social inclusion and equitable distribution of research and development findings can be obtained within the existing intellectual property framework, although these efforts have received less exposure.[34]