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Understanding gene-related patents

By Lauren Emr

The United States Patent and Trademark Office (USPTO) is the administrator of our patent system, and takes its direction on what subject matter is patentable from Congress and our reviewing courts. A patent grants the holder, for a finite term, the right to exclude others from making, using and selling the patented product or process, and can demand a royalty on any commercial gain derived from it. The current term of a patent is twenty years from the date of filing. The Patent Act of 1952, specifies four basic statutory requirements that must be met to obtain a patent: (1) the claimed invention must be statutory subject matter (i.e. machine, method, manufacture, or composition of matter); (2) have utility; (3) it must be novel and not been obvious to a person having ordinary skill in the art at the time the invention was made; and (4) it must be fully and unambiguously disclosed in the text of the patent application so that the skilled practitioner would be able to practice the claimed invention.

Around one hundred years ago, the courts began to rule that isolated and purified products of nature were eligible, as compositions of matter, to be patented. For example, Bayer obtained a patent for aspirin as a pure compound in 1899. The active ingredient in aspirin, salicylic acid, is derived from

salicin from the willow tree.

The most significant ruling on the patentability of biological products occurred in the Supreme Court's landmark decision in *Diamond v. Chakrabarty*, 447 U.S. 303 (1980). The *Chakrabarty* decision ruled that genetically engineered bacteria were patentable. This was the first ruling that a composition of matter could be alive. Chief Justice Burger cited the Congressional report accompanying the 1952 Patent Act in noting that "Congress intended statutory subject matter to 'include anything under the sun that is made by man.'"

Many commentators believe the *Chakrabarty* decision sparked the tremendous growth of the biotechnology industry. In reality, patents have been integral to the US. biotech industry's growth. The pharmaceutical industries are research intensive and mostly funded by the private sector. Hence, the private sector looks for security in their investments through patents and other intellectual property. Without such incentives, research into diseases and cures would arguably be significantly stifled.

Today, in the wake of the completion of the Human Genome Project, the patenting of gene-related inventions is the center of much controversy. Gene-related patents refer to patents for either

DNA (or associated materials such as RNA) as well as methods of using DNA. DNA and RNA are the building blocks of genes.

Genes are lengths of DNA that carry hereditary information and determine the structure of proteins. Although genes get a lot of attention, it is the proteins that perform life functions such as directing a cell to divide. When a gene is activated it is said to be "expressed." An expressed sequence tag (EST) is a short length of DNA that does something, like tell a cell to divide, when expressed. If the statutory requirements are met, an EST can be patented as a purified molecule, just like aspirin.

The biggest hurdle such gene-related inventions face is satisfying the utility requirement. In the past, at best nominal, or "throwaway utilities," would have allowed one to cross the utility hurdle for getting a patent for a gene. For example, if a gene was isolated from a cell, but the function of the gene was not known, the gene could be used to identify the cell, thus, satisfying the utility hurdle.

As of the most recent utility guidelines issued by the USPTO, the utility of a gene must be specific to the gene sequence in question, have a real-world utility, and be credible to a person of ordinary skill in the art. "Throwaway utilities" are no longer satisfactory.

Some of the controversy associated with gene-related patents is a result of discoveries from the Human Genome Project. In particular, it has been discovered that a single gene may code for multiple proteins. Therefore, the following issues arise: What if someone applies for a patent for a gene that expresses a particular protein, and someone else applies for a patent for the same expressing a different protein? Does the first patent holder have the rights to all of the proteins expressed by the gene? Keep in mind that more than approximately 20,000 patents on gene-related inventions have already been granted.

Another controversy concerns whether the goals of the patent system and those of science and medicine are properly balanced. Some are concerned that patent holders will impose on users of their inventions licensing terms that will impede medical research or restrict patient access to affordable testing. For example, Myriad Genetics Inc. owns patents for two important genes used for breast cancer screening, namely,

BRCA1 and BRCA2. Only laboratories that have been licensed by Myriad can perform breast cancer screening tests using the two genes, all others can not offer such testing.

Aside from the above controversies, there are many commentators who still hold the position that genes are naturally occurring substances that should not be patented. In the most recently issued guidelines, Congress has officially stated that individual human genes can indeed be patented if they are extracted from a cell and copied, and their practical use is described in careful detail. Still, many question whether it is moral to attribute ownership rights on a fundamental unit of human biology, such as a gene.

In defense of gene-patenting, many have argued that the gene-related patents that are being issued cover an industrialized product that has been isolated and purified by humans. Only the DNA that exists in the laboratory can be patented, not DNA in humans or animals. Some have made the analogy that genes are merely complex chemicals

purified from nature, much like aspirin for example. Such purified chemicals have long been held to be patentable. The USPTO has issued hundreds of patents to products extracted from nature for pharmaceutical or diagnostic use, including clot-busting proteins to treat stroke, antigens for the detection of cancer, and antibodies to treat infection.

The current trend in medicine is moving towards using our genetic blueprint to develop preventive and protective therapies. Research into isolating and understanding individual genes is key to this trend. Ultimately, one must weigh the benefits of encouraging such research against the potential detriments of giving a twenty year exclusive right to an entity for a gene.

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