**Should Genetic Code Be Patented?**

John Salinas Lopez

Marked by the increases in microbiological research and technology, many research institutions, both public and private, have discovered genetic technology and gene[1] sequences that have promising potential. News reports flourish with breakthrough accomplishments dealing with genome[2] sequencing, gene development into protein expression, and even stem cell culture isolation giving rise to the potential for human cell cloning. Amidst all the scientific speculation, the occasion arises when a developing institution moves to protect their research investment by contacting a patent lawyer for consultation. As a vastly increasing amount of genetic code patents flood the United States Patent Office, society wonders whether or not genetic sequence should be patented. Furthermore, if patent is justified, what parameters and guidelines should be required? After conducting elaborate research, it is my conclusion that genetic code and sequence can be patented material, provided that the patent is not so biotechnically broad that it creates a monopoly or illegitimate patent protection based on lack of product or potential product specificity. I will share case studies demonstrating genetic code patent parameters that are too broad, proving that dangerously broad patents are monopolistic and devastating to the research industry as a whole. In contrast, I will provide insight into exactly how precise a biotechnological design should be in exemplifying the specific parameters necessary for a legitimate patent of genetic sequence.

Genetic code and gene sequence meets patent criteria under law based on three crucial arguments involving biotechnical development. These criteria offered by Professor Vernellia R. Randall of the University of Dayton School of Law justify genetic code as patent worthy material. The first argument recognizes the effort involved in locating, characterizing, and determining the roles coding genes play in an organism. This arduous process of scientifically intensive research elevates the discovery of the genetic sequence to the status of an invention, and not merely a discovery. Secondly, Randall argues that discoveries of this nature are expensive in terms of both laboratory time and money; therefore obtaining a patent may be among the only methods an institution can use to protect their research and personnel investments. Finally, patents by

*Law and Society Review at UCSB*, Volume 1 (2002).

their inherent nature promote original research and development, as patents facilitate the focus of effort in innovation and inhibit the effortless duplication of the arduous research process already explored and invented (Randall 2001).

In the emerging field of genetic engineering[3] , the innovations surrounding developing and manipulating genetic codes and biotechnological tools are certainly viable and worthy of patenting. The touchy dynamic that follows suit is defining the parameters necessary regarding specificity for the gene sequence and its purpose. If the gene or technique is patented under too broad of terms, the outcome can be problematic. As this case study will demonstrate, inappropriately broad patents tend to stifle innovative competition of researchers, especially in an emerging field of genetic engineering and recombination[4] . For instance, consider the Agracetus cotton patent case study as described by Seth Shulman (1995) in his special feature from *Technological Review* entitled "Patent Medicine". Agracetus, a subdivision of a major chemical company, designed a "gene gun" that functions to insert an expressive genomic sequence-containing vector into cotton plants, creating immunity to a devastating cotton disease. On the advice of counsel, Agracetus applied for patent protection that broadly declared claim to all genetically engineered cotton, regardless of the technology used. The U.S. Patent Office initially granted Agracetus the patent, and all other institutions conducting research in the area of cotton genetic engineering, including the U.S. Department of Agriculture, would be forced to pay royalties to Agracetus under patent law (Shulman 1995). As the proceedings continued, Agracetus refused to grant out licensing, thus forcing institutions nationwide to consider the elimination of their cotton research projects. Fortunately, the initial issuance of patent protection was overturned, and the cotton genetic engineering research field remains an oligopoly of several leading research institutes.

The new question in litigation requires the identification of the specific degree of patent protection that Agracetus is inclined to receive. In defining the parameters necessary to arrive at a fair patent, the parameters must avoid using the Plant Patent Act of 1930 as the only legal precedent and include the precedent set by *Diamond v. Chakrabarty* (1980) concerning utility patent in plants as well. The Plant Patent Act (PPA) protects the inventor of an asexually distinct and new variety of plant, including mutants, hybrids and newly formed seedlings, allowing for patent protection under those broad parameters (Bennett 1994). The *Diamond v. Chakrabarty* case set precedent in allowing issuance of patent for "any new and useful process, machine, manufacture, or composition of matter, or any new

useful improvement thereof," pertaining now under new precedent to plant life (Bennett 1994). Establishing viability for patent under this act and precedent of established utility has been widely effective in patenting plant genes, gene transfer vectors[5] , and transgenic plants[6] much like those used by Agracetus.

In further isolating the patent variation that Agracetus should receive, we examine an article by P. Lange (1994) entitled "'Patenting' of Living Organisms-Patents and Plant Breeders' Rights". Lange offers a precise parameter: "example of things suitable for patent protection are genetically manipulated constructs in plant material coding for specific proteins-such as virus resistance" (Lange 1994). Such a patent would certainly encompass plant material such as an insertion vector that is distinguished by the fact that it contains the expressed genomic construct necessary for the disease resistant phenotype[7] of the Agracetus cotton plant. As we consider these parameters, the only element of research and development that is eligible for patent are the genetic sequences inserted into the transfer vector, and the "gene gun" used to insert the transfer vector into the cotton chromosomes, and certainly not all genetically engineered cotton plants, independent of technique.

Unfortunately, such broad biotechnology patent claims are not always overturned in favor of a more precise remedy. Revisiting Shulman's article "Patent Medicine" found in *Technology Review* where he describes a case concerning the U.S. National Institute of Health (NIH). A senior researcher used gene therapy[8] on a human being for the first time ever in effort to treat a child with a rare blood disease. The U.S. Patent Office issued patent to NIH for protection of all ex vivo gene therapy, which under patent protects removing malfunctioning human cells and genetically altering the chromosome composition before re-insertion into the patient (Shulman 1995). Joseph Glorioso, head of the Department of Molecular Genetics and Biochemistry at the University of Pittsburgh in Pennsylvania, was quoted in the science journal *Nature* when asked how he and his colleagues felt: "deep despair [about the patent], it is analogous to giving someone a patent for heart transplants" (Malavich 1995). The importance of arriving at specific and concise parameters for a patent become terribly obvious when broad patents such as these manifest themselves and essentially shut out all other practical uses for a widely used technique such as cell therapy.

Essential to the biotechnical development adventure, we must understand that with the virtually completed Human Genome Project, a mad scramble to patent human gene sequences has begun, especially those sequences that have potential for development in HIV infection

therapy. HIV therapy research and human genomics demonstrate an example of genetic engineering that is inherently highly specific based on its scientific nature, especially when implications of patent protection arise. In HIV gene therapy research, the genome is scoured for nucleotide[9] sequences that in this case study are indicative of sequences that code for cell surface proteins lacking HIV virus receptors on the cell surface of a human cell. The discovery of the CCR5 HIV receptor gene within the genome is a highly specific sequence. When one of two receptor genes are knocked out, HIV loses affinity for the cell and greatly reduces the chance for infection to occur (Fields 1996). In presenting this gene sequence for patent, Progenics Pharmaceuticals made note of the functional specificity of the sequence, and the practical and applicable use of the gene in pharmaceutical production of protease inhibitors[10] and nucleoside analogs[11] which will be the practical line of attack of the HIV drugs that could be developed (Reuters 2001). Patent proposal such as the CCR5 HIV receptor gene exemplify the parameters of specificity that should be required to receive a deserving patent.

The analysis of both theories illustrates that patenting genetic code is justified in the discovery of sequences to the status of an invention based on the effort in characterizing the gene. Understanding that discoveries in genetic code and therapy are expensive is crucial; a patent is required to protect the investments. Finally, acknowledging how patents promote further research and development with the inhibition of duplication, especially with the CCR5 HIV receptor gene, functions to demonstrate the appropriateness of patents. It is crucial, however, to realize that broad parameters in patenting biotechnology, especially genetic sequences, can be extremely damaging and monopolistic, as with the cotton plant created by Agracetus, and the patent owned by NIH pertaining to cell therapy. The implementation of strict and precise parameters function to issue a legitimate and promising patent for an exciting breakthrough in the biotechnology industry.

**Endnotes**

[1] Gene- a unit of heredity;a segment of DNA specifying a particular protein or polypeptide chain (Madigan 2000).
[2] Genome- the complete set of genes present in an organism (Madigan 2000).
[3] Genetic engineering- the use of in vitro techniques in the isolation, manipulation, recombination and expression of DNA (Madigan 2000).
[4] Recombination- process by which genetic elements in tow separate genomes are brought together in one unit (Madigan 2000).

[5] Vectors- a genetic element able to incorporate DNA and cause it to be replicated in another cell (Madigan 2000).
[6] Transgenic plants- plants that stably pass on cloned DNA that has been inserted into them (Madigan 2000).
[7] Phenotype- the observable characteristics of an organism (Madigan 2000).
[8] Gene therapy- treatment of disease caused by a dysfunctional gene by introduction of a normally functioning copy of a gene (Madigan 2000).
[9] Nucleotide- a monomeric unit of nucleic acid, consisting of a sugar, a phosphate, and nitrogenous base that compose a strand of DNA (Madigan 2000).
[10] Protease inhibitors- a compound that inhibits the action of viral protease by binding directly to the catalytic site, preventing viral protein processing (Madigan 2000).
[11] Nucleoside analog- a component of genetic material used to inhibit retroviral replication within a host cell (Fields 1996).

**References**

Bennet, Virginia C. (1994) "Plant Biotechnology," Ed. Denneth D. Siberly. *The Law and Strategy of Biotechnology Patents*. Newton: Butterworth-Heinemann Publishing.

Fields, Bernard N. Ed. (1996) *Fundamental Virology.* Philadelphia: Lippincott-Raven Publishers.

Lange, P. (1994) "Patenting of Living Organisms-Patents and Plant Breeder's Rights In Patenting of Human Genes and Living Organisms," Eds. F. Vogel, R. Grunwald. Heidelberg: Springer-Verlag Berlin Heidelberg.

Madigan, Martinko, and Parker. (2000) *Biology of Microorganisms.* Prentice Hall.

Malavich, R. (1995, July 26) "Human Cell Therapy Patented." *Nature* 169.

Randall, Vernellia R. "Who owns the Human Genetic Code." Available: http://www.udayton.edu/- health/05bioethics/00ammons.htm [2001 July 24].

Reuters. (2001) "Biotech Firm Patents Key HIV Gene." Wired Digital Inc, a Lycos Network Site. Available: http://www.wired.com/nees/technology/0,1282,34386,00.html [2001 July 23].

Shulman, Seth. (1995) "Patent Medicine." *Technology Review.* Available: http://www.usis.usemb.se/sft/sfl4104.htm [2001, July 24].

**Case Cited**

*Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

**Statute Cited**

*Plant Patent Act of 1930*, 35 U.S.C. 161-164 (1930).