

# The Human Genome and Patenting

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It all began with Craig Venter, CEO of Celera Genomics. Dr. Venter's company, "sent 20,000 gene sequences to the United States Patent and Trademark Office, USPTO, claiming patents to the sequences and to procedures that would be used to diagnose disorders with the genes" (Duke).

What began with Celera Genomics is what the legal and scientific community calls "The Gene Patent Controversy".

With the completion of the Human Genome Project, the next step is to find out what the genes in our DNA are responsible for doing. Companies and researchers have the opportunity to obtain large economic gains in the exploitation of these genes if they are patented. The controversy is founded by several arguments including, but not limited to, guidelines for patenting genes.

Recently the USPTO finalized its patent utility guidelines, which are testing standards for the issuance of gene patents. These guidelines "reinforce the PTO's disfavor of granting patents for genes and fragments of unknown utility"(Duke). The ultimate purpose of the USPTO in regards to patenting genes is to disallow exploitations of the human genome so that research discoveries and the benefits to the public are not stifled.

The dangers associated with patenting genes could easily "impede the development of diagnostics and therapeutics" because of raised costs (HGPI). High royalties may "discourage product development" and the consumer will most assuredly have to pick up these higher development costs. Patents would also allow some biotech companies to monopolize certain "gene test" markets (HGPI).

The list for potential hazards involved with gene patenting goes on and on, but there are positives involved with patenting genes too. For example, money gained from a patent to fund a particular researcher is a great incentive to obtain a patent (HGPI). Researching a previously patented gene would be avoided, and patenting would most likely force research into "new, unexplored areas"

which would further progress in scientific discovery (HGPI).

Although the USPTO has revised its guidelines on the patenting of genes, there is still much ambiguity surrounding the patenting of genes and the utilities found therein. The USPTO has recently laid down utility standards in its 1999 Revised Interim Utility Guidelines. These guidelines have been "subject to considerable public debate" (Duke). The USPTO tended to focus on technical issues in its 1999 revision. Many scientists were vying for an all out prohibition on gene patents. The USPTO itself considered this and fully rejected it. The arguments that were presented for the prohibition of patents included the argument that, "an inventor should not be given a patent when he discloses only a single useful function for a particular gene"(Duke). Another primary focus of the guidelines is on the utility of the gene or gene fragments. Gene fragment utility presents a significant problem, and is the center of controversy surrounding patenting guidelines for genes.

Express Sequence Tags (ESTs), or gene fragments, are thought to be patentable because of their utility in research as probes (Duke). The argument against patenting ESTs is based on the idea that most of their physiological functions have not yet been defined; therefore their utilities outside of research are unclear, thus unpatentable (Duke).

The controversy surrounding these ESTs caused the USPTO to adopt the 2001 Utility Examination Guidelines (Duke). These new guidelines were a result of the US Supreme Court case: *Brenner v. Manson*. What the Supreme Court determined from this case was that "a patent is not given as a reward for the search of an invention's utility but, rather, a reward for actually discovering that utility" (Duke). The 2001 guidelines set up two utility tests adopted by the USPTO. These new tests have set the standard for gene patents to come.

The two tests are the "specific, substantial, and credible" test and the "well-established utility" test (Duke). The first of these tests, "specific,