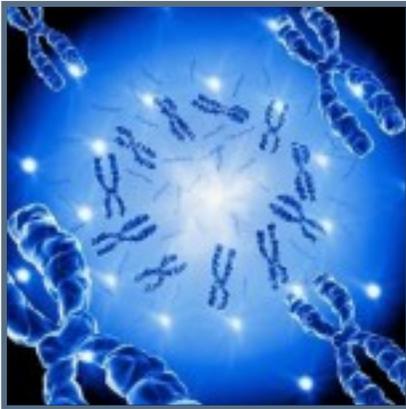


Guess Who Owns Your Genes

By Peter Leighton

The first U.S. patent for a chemical composition based upon human extraction was granted in 1906 for adrenaline. In 1980 the Supreme Court ruled that a live, human-made microorganism is patentable subject matter. The first human gene was patented in 1982. There are now about 3 million genome-related patent applications.



A very important federal lawsuit filed by the ACLU and Public Patent Foundation of Cardozo School of Law is now being considered (*Association for Molecular Pathology, et al. v. U.S. Patent and Trademark Office, et al.*) which questions the ethical implications of “gatekeeper” patents.

Relevant in light of the healthcare crisis we are immersed in, this case brings to light concern about “ownership” of genes and the restriction of research surrounding those genes. The question before the court is whether these patents impede research, increase medical costs and retard the advancement of health. What the court will not contemplate is the moral and ethical questions entangled within.

You see, a patent holder who “owns” a gene can restrict research into that gene and charge whatever they like for the tests related to “their” genes, which are becoming ever more critical to patients that may need to determine if there is a genetic link to certain diseases. In the ACLU case against Myriad, women who fear they are at risk for breast or ovarian cancer must purchase Myriad’s \$3,000 test. By the way, Myriad’s profits are up 67% for the last quarter.

Because of these exclusive patents, doctors are unable to validate or verify the tests with a third party or independent laboratory. The ACLU contends that the development of treatments and further gene research is being restricted because of the patent ownership issue. Furthermore, the practice of “patent stacking” —

multiple patents of various aspects of a single idea owned by different holders — increases healthcare costs as legal permission must be obtained from each patent holder and royalties mount.

And the ACLU is not alone; many major healthcare groups including the American Medical Association are against this practice. National Institutes of Health director Francis Collins has argued against broad gene patents stating, “The information contained in our shared instruction book is so fundamental, and requires so much further research to understand its utility, that patenting it at the earliest stage is like putting up a whole lot of unnecessary toll booths on the road to discovery.”

An alternative model that seems to work is already in place. In 1999 a non-profit foundation was established to find and map 1.8 million SNP’s (single nucleotide polymorphisms) — believed to affect predisposition to disease and influence drug response — and make the map publicly available. This model has acted like an open source code, encouraging thousands of genetic researchers to address gene-disease links and further genetic research. While we await the ruling in the ACLU case, it reminds us of the importance of these kinds of ethical issues and begs us to consider the true implications of fencing off the wilderness for the sake of profits.