

Patenting Your Genes

Myriad Genetics now owns a part of each cell in your body. Last month, a federal appeals court upheld the patents on two genes, the BRCA1 and BRCA2, which are linked to breast and ovarian cancers. More than a year ago, the U.S. District Court invalidated the patents, citing the unpatentability of a natural phenomenon. Scientists, doctors, corporations, and policy makers have debated the economic and ethical validity of biological patents since the 1970's, but the recent surge in development of genetic diagnostic tests and therapies brings the issue to a new level of urgency.

Diamond v. Chakrabarty was the first landmark Supreme Court ruling on biological patents. A genetic engineer working for General Electric developed a bacterium that could break down crude oil to be used for oil spills. The Supreme Court upheld the patent citing that human-made micro-organisms are patentable. On the other hand, the gene patents in question relate to discoveries of mutations on particular genes that correlate to a certain risk for disease, and the genetic screening tests do not involve a manipulation of the DNA structure other than through purification and sequencing of the DNA that are standard procedures for analyzing DNA.

Philosophy

Patenting is an essential economic concept used to incentivize innovation. The nature of research requires large amounts of investment into resources with no guarantee of success. Consequently, private companies and research institutions need to have financial incentives to take on that risk and make the investment in research. Economically, patents drive research and fund science's progress.

However, ethically, the same complaints against big pharmaceutical companies apply to biomedical patent holders. Myriad Genetics currently sells diagnostic tests for the BRCA1 and BRCA2 genes for \$3,000, and the nature of intellectual property rights gives Myriad a monopoly over this particular breast cancer screening market. Those who can afford it must buy the screening test from Myriad, and those who cannot afford it must do without. The Association for Molecular Pathology, one of the plaintiffs involved in the lawsuit against Myriad Genetics, claims that "molecular test services are medical procedures. As such, they should be widely available to promote optimal patient care, medical education, and medical research."

The unique ethical consideration is of whether or not research institutions can use patented genes to conduct further research. Due to the importance of genetics to protein-based drug research, diagnostic technique investigation, and the expanding commercial market for genetic information, the limited availability of genes may act as a barrier to research that can't be "worked around."

Currently

According to the Hastings Center, a nonpartisan bioethics research institute, there are about 5,000 patents on human genes. While the federal appeals court upheld the patents on the BRCA genes after years of lengthy and costly litigation, the U.S. Supreme Court may

have the last say in this matter. The U.S. Department of Justice has already released a brief demonstrating their views against patenting genes, but the U.S. Patent Office has taken the opposite stance.

Over the past few years, the technology for analyzing DNA has become much more accessible and nonmedical industries are capitalizing on it with ancestry tracing, identification, forensic uses. Theoretically, the decision to uphold patents on genes will influence the future of these commercial industries as well as that of the medical field.