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Who Owns Our Genes?

Bioethics and Law Forum

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A few weeks ago, President Bill Clinton and Prime Minister Tony Blair announced that the governments of the United States and United Kingdom would work together to make the fruits of the Human Genome Project available to the public. Much reporting of the announcement suggested that it signaled a challenge to patent claims by researchers, universities, and biotechnology companies. The reaction was shared by investors as stock prices for these companies fell sharply. But what does the announcement change, if anything; and what are the fundamental issues with the ownership of genetic information?

The Human Genome Project is producing the first complete sequence of the human genetic code. That sequence is a string of about 3 billion base pairs of DNA, but it is just the beginning of our understanding of the human genome. The most important steps are yet to come. What do the sequences of base pairs code for, what does their product do in the human body, and how do changes in the correct code affect human health?

Researchers and biotechnology companies are working to answer these questions and their work requires access to the complete genetic code. So the code itself is a tool in research rather than its endpoint, and the Clinton-Blair announcement underscored the need to preserve free access to this basic information.

In fact, the announcement doesn't do much to change the state of affairs. There are parallel efforts to sequence the entire human genome; one public, the other private. The public effort, largely funded by the National Institutes of Health as part of an international consortium, puts huge amounts of new genome information on the Web on a daily basis. The private sector competition, from a company called Celera Genomics, produces genome information at about the same pace, but sells access to its database by licensing users, who pay a fee.

Genome information is, in effect, already a public good because anyone can access the public database on the Web. What Celera offers users is a more sophisticated tool by which to manipulate and search. But it should be the same genomic information available to the public—genomic information that is not protected by any patent.

By using this basic information about the genome we have begun to unravel what our genes mean—predicting increased risk of disease or coding for characteristics such as personality traits. The next steps will offer real leaps forward in prediction, diagnosis and, eventually, therapies. And the companies and institutions that pay for the research leading to genetic applications have begun to successfully protect their efforts with patents.

The system of patents exists to protect the interests of both inventors and society. Inventors have the incentive of a limited monopoly on their innovations, allowing them to sell or license their products or techniques for profit. Society benefits by the advancements of innovation and the full disclosure of whatever has been patented.

But our system doesn't allow a patent for the discovery of a law of nature. Gravity couldn't be patented by Sir Isaac Newton—even if he was the first to describe it. Mapping the raw sequence of a gene is viewed much the same way, unless a scientist can show the function of a particular sequence, such as causing a disease such as cystic fibrosis. Such a gene would have obvious uses, such as developing tests or treatment for the disease.

Even with this limitation on patent claims, the U.S. Patent Office has granted protection for a number of incomplete gene sequences and, apparently, many more applications are pending. The Clinton-Blair announcement does nothing to address this issue.

Our 200-year-old patent system was never intended to address the question of patent protection for genes, and the slowly changing system, coupled with rapidly changing science, makes for strained public policy. This issue is becoming increasingly important, not only in this country, but also worldwide, as genetic sciences increasingly become a global effort with a global market.

The challenge will be to protect the rights of the innovators while preserving the public nature of the information they use. A patent system creates rather than recognizes such rights, and we make bad policy when we forget the difference.

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