

Patenting human genes thwarts research, scientists say

June 4 2009, By Robert S. Boyd

Rapid advances in biology and genetics are raising fresh concerns about the spreading practice of patenting human genes.

The U.S. [Patent](#) and Trademark Office has granted patents to at least 4,382 human genes, including genes related to Alzheimer's, asthma, cancer, muscular dystrophy and other serious diseases.

"Twenty percent of the [human genes](#) are currently patented," said Christopher Hansen, an attorney for the American Civil Liberties Union, which filed a suit last month challenging six patents on two genes that are connected to tests for breast and [ovarian cancer](#).

A gene patent gives its owner the exclusive right, for up to 20 years, to control its use for medical research, diagnosis or treatment.

"A gene patent holder has the right to prevent anyone from studying, testing or even looking at a gene," the ACLU lawsuit protests. "As a result, scientific research and genetic testing has been delayed, limited or even shut down due to concerns about gene patents."

Patent holders reply that they have a constitutionally guaranteed right to protect their inventions in order to pay the heavy costs of genetic research and development.

Though gene patents are lawful, many scientists, health professionals and patients' organizations object that the patents are stifling research and

interfering with patient care.

"Patents are meant to protect inventions, not things that exist in nature like genes in the human body," Hansen said.

"Questionable patents are too easily obtained and are too difficult to challenge," the Senate Committee on the Judiciary declared last month. "An industry has developed in which firms use patents not as a basis for producing and selling goods but, instead, primarily for obtaining license fees."

The patent war is being waged on several fronts.

Congress is weighing legislation that would make it easier to challenge patents. The National Institutes of Health released a 136-page draft report on the problem this spring. The National Academy of Sciences and the Federal Trade Commission have held multiple hearings.

The ACLU suit was filed in federal district court in Manhattan on behalf of the American College of Medical Genetics, the College of American Pathologists, other research organizations and individual patients. The defendants are Myriad Genetics, a pharmaceutical firm in Salt Lake City, and the University of Utah Research Foundation, which sponsored the research.

The patents give Myriad Genetics the exclusive right to test women for mutations in two genes, known as BRCA-1 and BRCA-2, which may indicate a genetic susceptibility to breast or ovarian cancer. A woman who tests positive might decide to have her breasts or ovaries removed.

"The effect of the patents has been to stifle clinical practice and research on the genetic predisposition to breast and/or ovarian cancer," the ACLU said. "The public, and in particular women, have suffered unnecessarily

as a result."

In response to news media queries, Myriad Genetics said it thought that its patents were valid and that it intended to defend them vigorously.

The House of Representatives and the Senate are considering bills that would, among other things, make it easier to challenge existing patents. The Senate Judiciary Committee approved its bill May 12. The House Committee on the Judiciary has held hearings but hasn't yet approved its version. If it passes, the bill would be the first major change in patent law in more than 50 years.

Patents have a venerable history. The U.S. Constitution (Article 1, Section 8) provided for a system of patents in order to encourage innovation and industrial progress. The goal was to reward inventors for their discoveries and prevent competitors from using their work without paying for licenses.

However, no patents on living things were granted until 1980, when the Supreme Court, by a vote of 5-4, approved a patent on a microbe that had been modified to dissolve oil spills.

The court's decision opened the floodgates. More than 3 million gene-related patent applications have since been filed with the U.S. Patent and Trademark Office.

Multiple patents have been issued on different parts of a single gene, creating a "traffic jam" blocking investigators from working with that gene.

Fiona Murray, a professor of management at the Massachusetts Institute of Technology in Cambridge, reported a "significant decrease in the rate of follow-on research after patents on gene sequences have been filed

and granted."

The Patent Office estimated that about 52,800 patents have been granted related to genes, fragments of genes, genetic processes and bits of DNA as small as a single letter change in the genetic code.

ON THE WEB

More on gene patents: www.ornl.gov/hgmis/elsi/patents.html

A National Institutes of Health view of gene patents:

oba.od.nih.gov/oba/SACGHS/SACGHS

[%20Patents%20Consultation%20Draft%203%209%202009.pdf](#)

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