

# Who Owns Your DNA?

## Why patenting genes is a bad idea.

BY SHARON BEGLEY



EVER SINCE THE first human gene was patented in 1982, there's been a near-universal "What?!!!" when people hear that it's legal for someone to own the rights to our DNA.

Blame the Constitution, which empowers Congress to give inventors "the exclusive right" to their discoveries; the patent office, which interprets "discoveries" as including genes; and the courts, which have said similar patents "promote the progress of science," as the Framers wrote. So far, all that has trumped complaints that patents on human genes (of which some 40,000, covering about one fifth of the genome, have been issued) "halt research, prevent medical testing, and keep vital information from you and your doctor," as novelist Michael Crichton wrote in 2007. But maybe not for much longer.

In the first lawsuit of its kind, the American Civil Liberties Union and the Public Patent Foundation of Cardozo School of Law argued last week in federal court in New York that patents on breast- and ovarian-cancer genes held by Myriad Genetics are unconstitutional because they restrict research and thus violate free speech. I defer to others on the legal merits here. But the scientific issues, while no slam-dunk, have become serious enough in the past few years to call into question whether gene patents, meant to pro-

mote research, instead impede it, with no offsetting benefits.

Not to be heartless, but we have to put aside arguments that the patents hurt patients because Myriad charges so much (\$3,400) for BRCA tests, which doctors recommend for women with a family history of breast or ovarian cancer. "I can't afford it!" doesn't invalidate a patent. (Try that with Apple's iPad patents.) Nor does the fact that the exclusive patent prevents physicians from getting independent confirmation of genetic-test results, and women from getting a full second opinion. True, but,

legally, tough luck. The free-speech argument—that the patent restricts research—is therefore the plaintiffs' best hope.

On the surface, the patents don't seem to impede research. Thousands of BRCA papers have been published, and in surveys few scientists say patents are an obstacle to research.

But *few* isn't *none*. And the survey results may reflect the fact that many patents are cheap to license and are unrestricted, says law professor Timothy Caulfield of the University of Alberta; that is, the patentholder allows anyone to work on the gene for only nominal payment. Because Myriad doesn't, and has such a fierce reputation for enforcing its BRCA rights, these patents are different.

Thousands of BRCA tests, for instance, find "variants of unknown significance"—mutations that might or might not portend cancer. "Ordinarily, labs would test lots of people to determine the normal variation in a gene to see which variations are associated with

disease," says geneticist Wendy Chung of Columbia University. "But because of Myriad's monopoly, that hasn't happened. We haven't been able to freely study how BRCA functions."

Myriad's general counsel, Rick Marsh, insisted to me that this is not so. Although the patents give Myriad the right to prevent scientists from even looking at BRCA without permission, Myriad "has never told someone they cannot do [noncommercial] research on BRCA," he says. "The notion that Myriad has hindered research is incorrect." It has sent only one cease-and-desist letter to scientists, he says.

The recipients of that letter see it differently. Arupa Ganguly of the University of Pennsylvania had been testing BRCA to elucidate the range of harmless and dangerous mutations. Scared off, she stopped. "The idea was to discover how mutations other than the common ones affect the gene," says Penn's Haig Kazazian. Rather than fostering innovation, he says, gene patents "inhibit biomedical research."

If gene patents in general aren't hurting research, but the BRCA patents are, is that enough to invalidate all gene patents? The justification for patents is that they encourage innovation: make a discovery, reap the financial rewards. But I have real doubts that this applies in genetics. Discoveries, not dollars, are what motivate most geneticists. (I have criticized that before: because scientists care so little about turning basic discoveries into useful treatments, they have dropped the ball when it comes to helping patients.) If being first, not being rich, is what drives gene researchers, it is hard to see why society should tolerate patents on human genes that act as even the slightest brake on discovery.

**Patents are supposed to encourage innovation. But discoveries, not dollars, are what motivate geneticists.**