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## The Court Ruling That Says 'You Can't Patent Nature'

By [ABIGAIL FIELD](#) Posted 5:20 PM 03/30/10

After a U.S. District Court ruling yesterday, women in America may soon be able to get the same access to inexpensive, verifiable gene-testing for breast cancer that women in Europe currently enjoy. That is, if the decision is upheld on appeal, where it's almost certainly headed. At issue in the ruling was whether snippets of naturally occurring human DNA are patentable.

In his decision handed down yesterday, [District Judge Robert W. Sweet invalidated](#) Myriad Genetics' ([MYGN](#)) patents on human BCRA1 and BCRA2 genes and methods of analyzing them (*Association for Molecular Pathology, et al. v. U.S. Patent and Trademark Office, et al.*). Mutations of these genes are associated with breast and ovarian cancer, and Myriad's \$3,000 tests are currently the only way American women can determine if they have the risky mutations.

Although [Myriad is confident the patents will be restored](#) on appeal, Daniel Ravicher of the [Public Patent Foundation](#), co-counsel with the [American Civil Liberties Union](#) for the plaintiffs, is equally sanguine. "Judge Sweet's decision thoroughly analyzes the law and the science. You cannot patent nature. We fully expect the decision will be upheld on appeal." Ravicher predicts the appeal process will take about a year.

### "Very Pro-Consumer"

James Love, the American co-chair of the intellectual property committee of the [Trans Atlantic Consumer Dialogue](#) and director of [Knowledge Ecology International](#), notes that several countries have multiple providers of gene tests for breast cancer because those governments have refused to enforce the patents. And in France and Belgium, the patents were invalidated by statute. ([Since 2002 France has funded](#) cancer gene screening at the national level.)

"This is a very pro-consumer decision," says Love, "it's going to make it much cheaper for people to get the tests they need." The disparity between access to cheap tests for women in Europe and the U.S. is deeply ironic given that the U.S. National Institutes of Health funded as much as a third of the foundational research underlying the invalidated patents, according to Judge Sweet's opinion.

Plaintiffs in the Myriad case included American women who couldn't afford Myriad's tests and/or who wanted to verify Myriad's results by having a different lab perform the tests. Other plaintiffs include scientists at the University of Pennsylvania, Columbia University, Emory University and New York University, all of whom have the skills and equipment necessary to begin offering the same testing Myriad does. They're also willing and ready to do so, although they may wait until the appeals process ends before entering the marketplace.

By having these labs -- and any others that step forward -- compete with Myriad, people can expect testing to get better as well as cheaper. Notes Love: "These patents were anti-science, anti-innovation, and anti-consumer."

### **A Major Impact on an Entire Industry**

If upheld, the decision transforms the patent landscape far beyond Myriad's breast cancer genes. After all, some 20% of human genes are already patented. All existing patents that are based on "isolated [naturally occurring] genetic sequences and correlations between mutations in those sequences and propensity for disease," will be unenforceable, explains Ravicher, and no new patents for such DNA will be issued.

Ravicher elaborates that, under Judge Sweet's opinion, DNA would be patentable only if it was akin to the bacteria in the U.S. Supreme Court Case [\*Diamond v. Chakrabarty\*](#). That bacteria was created by engineering DNA to produce an organism with a crude-oil-digesting property not found in naturally occurring bacteria. The high court referred to it as "man-made." Other patentable areas would continue to include "new drugs, new treatments, new methods of isolating genes," Ravicher adds.

In its summary judgment brief, Myriad recognized the transformational impact of invalidating its patents. It starkly warned: "Such a ruling would lead to the invalidity of thousands of biotechnology patents, and effectively unravel the foundation of the entire biotechnology industry. Numerous therapeutic drugs and diagnostic tests in development would be jeopardized. The very existence of the fledgling personalized medicine field would be threatened."

However, [Myriad's press release](#) issued following Judge Sweet's decision seemed to undermine that claim. It says: "[W]e do not believe that the final outcome of this litigation will have a material impact on Myriad's operations due to the patent protection afforded Myriad by its remaining patents." Perhaps the statement just reflects Myriad's confidence in victory on appeal. But if so, why the word "remaining"?

### **Closely Watched**

This case's potentially broad ramifications are what drove so many groups to file "friend of the court" [briefs](#). Organizations in support of the plaintiffs included the American Medical Association and other doctors' groups; the March of Dimes and other patient groups; the National Women's Health Network and other women's rights groups; and the International Center for Technology Assessment and other public policy groups. Organizations supporting Myriad included the Biotechnology Industry Organization, America's largest biotech trade organization; the Boston Patent Law Association; Rosetta Genomics; and BayBio, a life-sciences trade organization.

Clearly, many eyes will be glued to the appellate courts as yesterday's ruling gets further scrutiny.

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