

What's at Stake in the Supreme Court Decision in 'AMP v. Myriad Genetics'

The outcome will effect far more than just the genetic test for breast cancer.

Rose-Ellen Lessy, June 5, 2013

Do you own the rights to your own genes? Only 59 percent of the time, according to one recent study; the other 41 percent of the genes in the human genome have already been patented. This means that once your blood is drawn, nearly half of your genetic material cannot legally be isolated, studied or tested by anyone but the patent holder.

Not all institutions and corporations enforce their patents. But some do: one genetic testing company who has been very aggressive in policing its patent rights—Myriad Genetics—is in the midst of a Supreme Court battle over their right to control the use of two genes—called BRCA1 and BRCA2—which, when damaged, lead to a very high risk of breast and ovarian cancer. It's estimated that as many as one in every 400 American women carries one of these mutations.

On April 15, the Supreme Court heard arguments in *Association of Molecular Pathologists v. Myriad Genetics*, addressing Myriad's right to hold the BRCA gene patents. The suit was first initiated in 2009 in New York Federal Court by an unusually diverse coalition of plaintiffs, including the ACLU; several professional associations of research scientists, including the Association for Molecular Pathology and the American College of Medical Genetics; individual researchers; women's health and breast cancer advocacy groups Breast Cancer Action and Our Bodies Ourselves; and individual women who have breast and ovarian cancer. (Notably absent from this list: the Susan G. Komen Foundation. Interestingly enough, Myriad is a Komen donor.) In 2010, a New York federal court ruled against Myriad, invalidating all of Myriad's gene patents. But an appeals court overturned the ruling a year later. Now the Supreme Court is weighing the case.



Christopher Hansen, a lawyer from the ACLU, delivered the oral argument before the Supreme Court, emphasizing that genes are “products of nature” and thus are ineligible for patent protection, asking, “What exactly did Myriad invent? The answer is nothing.” Myriad's lawyer countered this claim by insisting that in snipping the individual gene from the DNA sequence, Myriad is in fact creating a new product. He argued that “know[ing] where to snip” constitutes a new invention.

At the center of the Myriad case is a question that extends well beyond the parameters of breast and ovarian cancer: Is it even legal for the US Patent and Trade Office (USPTO) to issue patents for genetic material? Over the past two decades, the USPTO has issued thousands of gene patents. As Supreme Court Justice Elena Kagan commented during the Myriad arguments, “The Patent Office seems very patent-happy.” And some of these patents, like Myriad's BRCA patents, are stunningly expansive: one corporation can legally control and charge licensing fees for *all* uses of a particular gene. So the study of *any* disease that may have a genetic component is potentially at issue in this case. Will scientists and doctors be able to choose what genes they study and what treatments they develop, or will the corporations who own these genes be able to dictate the terms under which science and medicine may proceed?

As the plaintiffs in this case have argued, Myriad's actions—which have included sending cease and

desist orders to other laboratories—offer a stark illustration of the inequities perpetuated by allowing genes to be patented. Myriad is the only lab authorized to perform the BRCA analysis; they charge over \$3,000 for tests that many labs could easily offer for a small fraction of that amount. Myriad likes to say publicly that it has generously provided free tests to 5,000 women in the past three years. But don't be too impressed by these figures: that number means that Myriad has paid for less than 1 percent of all of the tests it performed during that period. As a point of comparison, about 20 percent of American women are uninsured.

Myriad's patent also inhibits research into better tests and treatments for women at high risk of developing a genetic form of breast or ovarian cancer. Because it holds a legal monopoly, Myriad has no incentive to develop better, more accurate or cheaper tests. And its patent has allowed it to prevent other researchers from developing better tests, too. It has had, according to the ACLU, "a chilling effect on research." Several of the plaintiffs in the original case describe the ways that their research or medical practices have been impeded by Myriad's patent.

Myriad's attorney argued that invalidating the patent would limit the incentive for future investments in biotechnology. But this argument is not especially convincing when it comes to genes: as the ACLU points out, the Human Genome Project succeeded in sequencing the entire human genetic code in spite of their disinclination to pursue any patents. In fact, allowing gene patents may actually inhibit, not encourage research and investment. As Dr. Harry Oster, one of the plaintiffs in the Myriad case explained in 2009: "In breast cancer genetic testing...we have seen no innovation in the past five years—since Myriad Genetics introduced its most recent test." If the goal of patent law is to encourage innovation, it has, in the case of genetic testing, failed miserably.

Implicitly pitted against the issue of investment incentive are the rights not just of scientists, but also of individual women. Not only are uninsured and lower income women particularly vulnerable to Myriad's monopoly, so are women of color. This is because, for some women, Myriad is unable to provide a clear yes or no answer, and instead returns a result that the woman's BRCA gene has a "variant of unknown significance." This means that a woman may—or may not—be at high risk for breast and ovarian cancer, a result that can be deeply confusing for patients and their doctors. Variants of unknown significance have been especially problematic for black, Latino and Asian women, who are disproportionately likely to get these ambiguous test results, and to thus have a more difficult time getting the information they need to make crucial treatment decisions. Because of Myriad's patent, women have been unable to get second opinions about ambiguous test results from other labs, and other labs, in turn, have been unable to work on developing more definitive tests.

Myriad's BRCA patents expire in 2015, so in a little over two years, other labs will be able to offer the tests that Myriad currently controls, regardless of the Supreme Court's case. So why is Myriad fighting the case? Not only because it makes nearly \$500 million per year on this test, and not only because it offers and is developing a number of other genetic tests, but because the implications of this ruling have the potential to effect the entire biotech industry. If human genes cannot be patented, then other products, like genetically modified crops, might also be up for reconsideration. Even so, a number of legal observers think there is a good chance that when the Supreme Court announces its decision in June, it will rule against Myriad, at least on the broader issue of gene patenting. Despite concerns by Justices Alito, Scalia and Kennedy about dampening enthusiasm for biotech investing, Justices Kagan, Sotomayor, Ginsberg and Roberts all expressed skepticism about the claim that merely isolating DNA constitutes a discovery. The Court has a chance to end the absurd and unjust practice of patenting the human genome. Let's hope they act.

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