

US top court to hear case on gene patents

April 13 2013, by Jean-Louis Santini

The US Supreme Court will hear arguments Monday on whether to allow private entities to patent genes they have isolated and identified, a decision that could have far-reaching implications for genetic research.

The nine justices will review a 2012 appeals court decision that allowed a [biotechnology company](#), Myriad Genetics Inc, to patent two [genes](#) it found had links to breast and [ovarian cancer](#).

But the ruling has drawn protest from a broad group, including associations representing some 150,000 researchers, doctors and patients, who are now asking the nation's top court to overturn it.

"Our [legal challenge](#) is based on 150 years Supreme court doctrine that says, under the patent act, products and [laws of nature](#) are not patentable," said lawyer Sandra Park of the [American Civil Liberties Union](#), which is leading the judicial battle along with the Patent [Policy Framework](#).

According to Park, extracting a gene from a cell to isolate it does not constitute an invention by itself.

"Myriad did not invent either of those qualities, just as a doctor that removes a kidney from the body for transplant does not somehow invent that kidney," she said.

"Obstacle" to research

For Joseph Stiglitz, a Nobel laureate in economics who teaches at Columbia University in New York, Myriad's two patents obtained in the 1990s create a "lack of access to testing but also a lack of access for further development of basic research."

Park explained that "because of Myriad's patent of the gene, no other scientists can look at these genes."

The "very broad" patent "precludes any laboratory or scientists from doing clinical or research work with these genes because isolation is fundamental to doing anything with them," she emphasized.

As a result, the researchers are unable to develop competing tests that may potentially be more effective than Myriad's to determine if a woman is a carrier of the mutations that predispose her to breast or ovarian cancer.

That's a crucial problem, said Ellen Matloff, director of cancer genetic counseling at the Yale Cancer Center, because Myriad's test falls short and fails to detect the mutated genes in some women.

"No one else can do testing, no one else can offer a more comprehensive test and unfortunately as a result of that, that will cost lives," Matloff lamented.

Moreover, with its monopoly, Myriad can bill more than \$3,000 for an analysis that, Matloff said, should cost a tenth as much.

But Myriad defends its patents and denies they cover mere products of nature.

"Myriad created synthetic molecules of DNA in the laboratory that are used to test patients for increased risk of breast cancer and ovarian

cancer," the company said in a statement.

"Those synthetic molecules are different from what is found in nature or the human body," it emphasized.

It maintained, as well, that the discovery of the two genes, the product of research that typically requires years of effort and large investments, ought to be protected.

Nearly 20 percent of the approximately 24,000 human genes are currently under [patent](#), some of which are associated with Alzheimer's disease or other cancers.

These patents are sometimes owned by private companies but also by universities and research institutes concerned with keeping them in the public domain to prevent companies from seizing them.

The Supreme Court's decision is expected in June.

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