

Patenting the human genome

May 24 2013, by Adrienne Wright

Can human genes be patented? That was the question posed by Alan J. Snyder, vice president and associate provost for research and graduate studies at Lehigh, and Lee Kaplan, scientific director of cellular and molecular genetics at Health Network Laboratories, at a panel discussion on campus this spring.

Snyder and Kaplan examined Association for [Molecular Pathology](#) v. Myriad Genetics Inc., an intellectual property case now before the Supreme Court that could have far-reaching implications for the scientific community as well as for ordinary men and women.

At the center of the case are genes BRCA1 and BRCA2, which made headlines recently when actress Angelina Jolie announced that she had tested positive for mutations of the gene and opted for a preventive [double mastectomy](#) to reduce her risk of [breast cancer](#).

After the genes were sequenced at the University of Utah, patents to them were licensed to Myriad Genetics through a tech transfer. Myriad has excluded outside companies and universities from studying the genes and testing for mutations that could lead to breast and [ovarian cancer](#). Instead, the company charges more than \$3,000 to administer tests itself.

"Eighty percent of the [human genome](#) is patented, but this is one of the few companies that actually enforces their patent to this degree," Kaplan said.

The intricacies of patent law

Previous [Supreme Court rulings](#), said Snyder, have set a precedent for what can be patented under the U.S. Patent Act.

"The definition from *Diamond v. Chakrabarty* is 'anything under the sun that is made by man.' In that case, the Supreme Court ruled that modifications to DNA are indeed patentable. The only things that are explicitly excluded from being patented are human life forms and so-called 'laws of nature.'"

Indeed, one of the central issues in the *Myriad* case is the "isolated DNA claim"—whether a gene taken out of the body qualifies as a [DNA modification](#) or as a product of nature.

"Is a gene carved out of a chromosome patentable matter?" Snyder asked.

The Supreme Court is expected to rule on this claim in late June, and Kaplan said the outcome could have a profound impact on scientific innovation and progress.

"There hasn't been much forward movement in the area of breast cancer research because labs aren't able to study this gene," Kaplan said.

"BRCA1 was discovered in 1994, so it kind of makes you wonder why there's no drug for this, why nothing has progressed in this field."

Myriad's monopoly on testing, said Kaplan, means that no one is looking over the company's shoulder to validate its work.

"*Myriad* developed their test to only look at a few points on the gene, so they would send results back and say an individual didn't have the mutation," she said. "Then in 2008 they came under pressure by the scientific community to test more and it turned out there were some gene rearrangements their tests weren't capturing."

A swath of people tested over a 10-year period, he said, may have been given false results.

"You now have these patients who have cancer and who could have had a mastectomy or hysterectomy during those 10 years if they had received accurate results," Kaplan said.

In the end, the ruling will come down to the Court's interpretation of what can be patented.

"The question isn't whether the genes in your body are patentable," Snyder said. "It's whether taking them out of your body and isolating them makes them substantially different."

Provided by Lehigh University

Citation: Patenting the human genome (2013, May 24) retrieved 2 May 2024 from <https://medicalxpress.com/news/2013-05-patenting-human-genome.html>

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