

Association of University Technology Managers[®] Advancing Discoveries for a Better World[®]

Supreme Court Says Human Genes Aren't Patentable

Today the U.S. Supreme Court issued <u>its unanimous decision</u> that human genes cannot be patented. The decision is in response to the case of Association for Molecular Pathology, et al. v. Myriad Genetics, Inc. et al.

The Supreme Court decided:

- 1. Genomic DNA as it exists in nature, e.g. within a person, is not patentable subject matter
- 2. Genomic DNA isolated from nature, e.g. now cut away from other genetic material and completely outside of a person, is not patentable subject matter
- 3. cDNA, artificially constructed DNA containing some sections of isolated genomic DNA, is patentable subject matter

Note: The Supreme Court's decision does not address the additional requirements for patentability, such as novelty and non-obviousness. The Court did not analyze inventions related to the methods of using the DNA sequences.

AUTM's Position: AUTM agrees with both parties and the Court that diagnostic tests should be available for the benefit of the public. It supports the encouragement of rapid medical innovation, applied and practical biotechnology, university basic genetic research, collaboration among universities and the medical community and translation of genetic discoveries into tangible medical tests. AUTM believes in the importance of intellectual property protection and remaining competitive with other countries in developing lifesaving technologies.

Background:

Myriad developed genetic tests for identifying mutated DNA sequences associated with increased risk of a particular type of breast cancer which affects 5-10% of women. Normal versions of these DNA sequences code two tumor suppressor genes called BRCA1 and BRCA2, and the mutated versions of these sequences can indicate an increased likelihood of developing breast cancer. Women can use the test results and information regarding the presence of these mutant BRCA sequences to make educated decisions about their health management.

Like most scientific discoveries, basic and applied research at several U.S. universities and the NIH contributed to the discovery of the BRCA genes. Universities typically receive additional research funding from such discoveries, including from the companies who commercialize the discoveries.