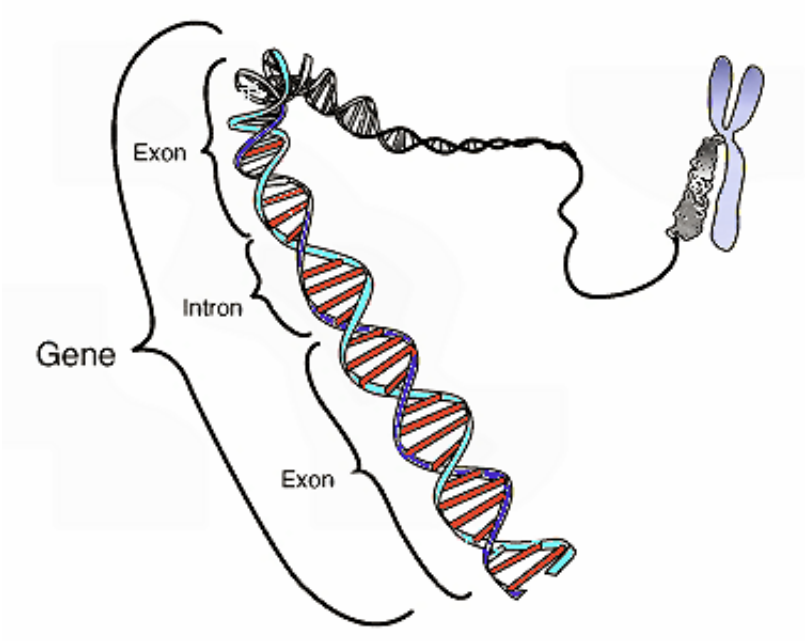
Are human genes patentable?

April 11 2013, by Jessica Martin



This image shows the coding region in a segment of eukaryotic DNA. Credit: National Human Genome Research Institute

(Medical Xpress)—On April 15, the Supreme Court will hear oral argument in Association for Molecular Pathology v. Myriad Genetics, a case that could answer the question, "Under what conditions, if any, are isolated human genes patentable?" Kevin Emerson Collins, JD, patent law expert and professor of law at Washington University in St. Louis, believes that layered uncertainties make this case an unusually difficult case in which to predict the outcome.

During the early 1990s, Myriad Genetics made important scientific discoveries related to mutations in the BRCA 1 and BRCA 2 genes, which are biomarkers for increased risk of breast and ovarian cancer. Based on this work, Myriad sought, and obtained, patent protection for "isolated" DNA molecules that embody these sequences.

The Supreme Court's opinion in Myriad will determine whether Myriad's gene patents are valid or, alternatively, whether they were improperly issued from the beginning.

"The legal controversy centers on patent law's 'products of nature' doctrine—a doctrine that prevents the patenting of newly made products that do not display a 'marked difference' from naturally occurring products," Collins says.

"A perfectly circular section cut out of a leaf of a newly discovered plant may be technically new at the time that it is first made – and it may be socially useful if the leaf contains chemicals that are natural wound healers, but it's likely an unpatentable product of nature because there is no marked difference between the newly created product and the naturally occurring product.

"Importantly, the Myriad gene patents only encompass DNA molecules in an 'isolated' state, separate from the remainder of the chromosome in which they exist in a human body, and they thus describe molecules that were technically new when Myriad first made them."

The question before the Court is whether the structural and functional differences between naturally occurring DNA molecules and DNA molecules in an isolated state is sufficiently significant to constitute a "marked difference" and to sanction the patenting of the isolated DNAs.

Behind the legal controversy is an economic controversy that may (or

may not) influence the Supreme Court's pronouncement on the products of nature doctrine. "The social costs of the exclusive rights to inventions granted by patents are normally justified by the incentives that patents provide for self-interested entities to invest in research and development and generate the socially valuable inventions," Collins says.

However, under some circumstances, there are legitimate concerns that the incentive-based benefits of patents may not outweigh these costs.

"One function of the products of nature doctrine is to ensure that the basic tools of scientific and technological work are not constrained by claims of patent rights and remain free for all to use as inputs into future research," says Collins.

"To the extent that isolated genes are essential technological and scientific building blocks, the costs of Myriad's gene patents in the form of slower innovation in the future may be so great that they will outweigh the benefits of the patent-induced incentives that speed up the creation of the isolated genes themselves."

The verdict

Collins says it is difficult to predict how the Supreme Court will decide this case because of three compounded uncertainties.

First, the Supreme Court has to date not offered a clear legal framework for identifying products of nature, so it is unclear how high a hurdle the markedly different standard will prove to be.

Second, it is unclear how strongly the Court's legal determination will be influenced by the underlying economic concerns about the privatization of the building blocks of technological progress.

Third, the relationship between the Supreme Court and the Federal Circuit Court of Appeals—the court that authored the opinion below in Myriad—is not likely to lead to much of any deference.

"Recent Federal Circuit patent decisions have been poorly received by the Supreme Court," Collins says. "The Federal Circuit upheld the patentablity of these genes, but, given recent history, this is not much of an indicator as to Supreme Court will handle this case."

Provided by Washington University in St. Louis