PALEY ROTHMAN
ATTORNEYS AT LAW

Gene Patent Protection Still A Work In Progress

By

The Supreme Court recently ruled that naturally-occurring human genes are “products of nature” that are not eligible to be patented. At the same time, however, the Court held that artificially-created DNA, so-called complementary DNA or cDNA, is patentable, because it is not naturally occurring. The 9-0 decision in Association for Molecular Pathology, et al. v. Myriad Genetics, Inc., et al., No. 12-398 (June 13, 2013), written by Justice Clarence Thomas, invalidated Myriad’s patents on the BRCA1 and BRCA2 genes associated with breast, ovarian and other cancers. The ruling has been hailed by patients’ rights groups, civil liberties advocates and the biotech industry as a milestone ruling that will encourage innovation in biotech research and benefit patient care. It is also likely to have application in other non-human areas of research, such as plant, animal and microbial genes.

Notwithstanding the case’s anticipated significance, its short and long-term implications may not be as far-reaching as some have indicated. For those who are pleased with the outcome, the expectation is that the decision will allow companies to perform genetic testing and enable researchers to conduct experiments on any part of natural human DNA without fear of running afoul of a blocking patent. One company has already announced that it will make BRCA 1 and 2 genetic tests available for around $995, roughly 25% of the price charged by Myriad Genetics. Going forward, genetictests undoubtedly will be forthcoming to look for multiple genetic mutations besides the BRCA mutations.

Myriad Genetics, despite its loss before the Court on its human DNA patents, put a positive spin on the loss, pointing out that the decision upheld the company’s ability to maintain its cDNA patents on synthetically-created DNA sequences, since cDNA is not naturally occurring. Moreover, the Court emphasized that while a naturally occurring gene is a product of nature and, therefore not patentable, both the *methods* used by scientists to isolate genes and new *discoveries* about the genes may be eligible for patent protection. As scientists increasingly try to improve upon nature, and synthetic biology consequently becomes an increasingly important area of research, synthetic biological discoveries will continue to be eligible for patent protection despite the Court’s decision.

The fact is that many of the gene patents would have expired in the not too distant future anyway. Myriad’s gene patents on BRCA 1 and 2, for example, reportedly will expire in 2016. And it may well be that older patents on genes may have no effect on more current genetic tests that only look at small parts of a particular gene.

At least one expert, Hank Greely, a bioethicist and law professor at Stanford University, thinks there may be a bigger question in the long term, namely, whether naturally occurring proteins or molecules can be patented, because many modern drugs incorporate ingredients that start out as naturally occurring molecules.

Our own view is that the Supreme Court chose to take a middle course that clears any obstacles posed by patents on naturally occurring human genes, while continuing to protect the products of innovation, such as synthetic genes, methodologies relating to the manipulation and uses of naturally occurring human genes and discoveries about genetic material

Arthur House represents biotechnology and pharmaceutical companies in the areas of drug and technology licensing and product development. He also is an arbitrator and mediator in domestic and international disputes relating to science, manufacturing and technology.

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