The Supreme Court nails it (and Myriad) No, you cannot patent a gene

By ACSH Staff — June 13, 2013

This morning’s unanimous Supreme Court decision [2] which overturned a lower Federal court decision allowing Myriad Genetics patent of two human genes is a groundbreaking moment in the history of biotechnology, and a case that will surely rank among the most noteworthy biomedical decisions of our time.

The genes in question are called BRCA-1 and BRCA-2; a woman with one of them has a greatly increased chance of developing breast or ovarian cancer.

The overarching question which has been an ongoing controversy since 1997 when the U.S. Patent Office granted Myriad’s patent of the two genes was whether genetic information, even newly discovered information, could be patented.

As ACSH’s Dr. Josh Bloom explains, there are two basic types of patents: composition of matter patents which cover new materials, such as new drugs or chemicals, and use (utility) patents, which cover a novel use of a pre-existing substance. The patenting of human DNA did not fit into either of these categories, and this created quite a stir.

Patents, which last for 20 years in the US, have only one purpose to prevent others from using an invention for commercial purposes during the period of exclusivity. They do not give permission or approval to market anything. They simply exclude others from doing this. Patent laws protect inventions, and are absolutely essential in fostering innovation.

Dr. Bloom adds, one of the fallacious arguments often heard regarding this case is that one cannot patent anything from the natural world. This is both wrong, and irrelevant here. Natural products have long been covered by use patents (e.g. cancer drugs). Although the chemicals or drugs in question are not novel, their use for new indications can be, and this can be just as innovative as discovering something entirely new.

But the Myriad patent broke new ground in attempting to patent the actual genes. If the company had simply filed a use patent on the BRCA assay the test for the gene, rather than on the gene itself there would be no controversy. They would have had proprietary protection for their test and would be able to charge whatever they wanted for its use. This is nothing new.

But by claiming the actual gene rather than just the test derived from the discovery of the gene, they took patent protection to the next level, one that many scientists and lawmakers were uncomfortable with. This extra claim, had it held up, would have prevented another company from even developing another (and possible superior) test for the BRCA genes because they would need to get a licensing agreement from Myriad for anything they discovered related to the BRCA
genes, effectively shutting down future work by anyone other than Myriad in this area. This is the real essence of the case.

The Supreme Court took care of this, and did so unanimously, which Dr. Bloom found astonishing, since I cannot imagine the 9 of them agreeing on anything, including whether or not their own courtroom was on fire. But I have to give them credit here.

Although the decision is huge, Myriad will do just fine. In fact, their stock price is up 10 percent today. Although they cannot patent the genes, their patent protection for the assay to detect them is more than adequate to protect their intellectual property. And they deserve it. Their assay will save many lives, and they should be rewarded for it. They just went a little too far.


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