

OP ED GENE PATENT

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(hed)Unrestricted Research vs. ROI

The U.S. Supreme Court's 9-0 ruling that isolated human genes are not patentable will affect selected segments of genetic and biological research, while continuing to grant patent protection to synthetic or modified DNA.

Intellectual property experts warn that the ruling has adverse implications for research in stem cells, purified proteins and small molecules isolated from plants, as well as personalized medicine, which promises to devise treatments derived from the patient's own genetic material.

In the ruling, Myriad Genetics lost its patent protection on mutated BRCA-1 and BRCA-2 gene sequences that signal an increased risk for breast and ovarian cancer, breaking its monopoly on the BRCA diagnostic market and opening it to competition. But Myriad's approximately 500 different patent claims to cover various aspects of using BRCA-1 and -2 remain unaffected by the Court's decision.

Patent attorney Konstantin Linnik says the litigation leading to the Court's decision was "very much a political statement," While cancer patients may have a gut reaction that their genes should not become someone else's property, investors in new technology need to have the assurance of patent protection. "If you look at the fundamental principles of the patent system, which is to disclose so that others can build, that incentive is reduced," Linnik says. "That's an unfortunate outcome."

The ruling will also make it more difficult, though not impossible, to protect early discoveries, but it leaves room for patent claims to chemically modified sequences. The patent allowability of cDNA, which has been altered in the lab, will maintain incentives for investors.

Patent attorney Greg Williams of Pepper Hamilton LLP says patent holders in areas affected by the ruling will likely be motivated to review their existing patents to see what can be sustained, and they have the option to seek to add claims through a re-issue. Pending applications can be amended during prosecution before the patent office. But, he says, within the last 8 to 10 years, the number of patents for isolated DNA has generally trended downward. The patent office has gotten more restrictive, but not based on patent-eligible substance (for example, isolated DNA). Instead, it has placed more emphasis on novelty and being non-obvious, i.e. not readily apparent to someone with experience in the art. The Court ruling notwithstanding, now that the human genome information is all in the public domain, he asks, what is there that is not obvious?

The pressure to democratize research, and the trajectory of innovation itself, have become an irresistible force. But the immovable object is the market's need for return on investment.

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