

Patent flap could hurt biotechs

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The prospect of a federal appeals court ruling invalidating thousands of biotechnology patents has caught the attention of Colorado companies.

While the implications aren't completely clear yet, the case is one of the most talked-about issues in intellectual property law today, said John Posthumus, head of the Colorado Bar Association's patent section.

"Arguably it could invalidate and implicate over 10,000 existing patents in the patent office — which is really huge," said Posthumus, a shareholder at Denver-based Sheridan Ross PC.

The case stems from a lawsuit in which the U.S. Department of Justice took an unexpected stance: that naturally occurring genes shouldn't be patented.

The case's impact will be determined by future court rulings, and how broad or narrow those rulings are.

Biotechnology observers around Colorado have been trying to determine what the case could mean for them.

The lawsuit involves Myriad Genetics, a Salt Lake City biotech that developed tests for the genetic mutations making women susceptible to breast and ovarian cancer.

The diagnostic test, which grew out of a patent issued on Utah research, has become the medical standard. Thousands of women have paid \$3,000 or more to take the test.

The American Civil Liberties Union, medical advocacy groups, doctors and

breast-cancer patients sued Myriad and the U.S. Patent and Trademark Office (USPTO) last year, arguing the patent should be invalidated because it covered genes.

A lower court sided against Myriad and USPTO in spring. They appealed.

The DOJ last month filed a friend-of-the-court brief in the appeal that, to the biotech industry's surprise, argued genes are part of nature and shouldn't be patented.

The DOJ's brief compared genetic material to coal, arguing that extracted coal can't be patented because the stuff that occurs in nature is the same as what's mined.

That puts the DOJ's stance in conflict with the USPTO's long-held practice. The Myriad appeal counted 2,645 patents with claims to isolated DNA and more than 50,000 patents covering some nucleic acid sequence.

Some wiggle room

But the DOJ's stance leaves room for researchers to patent genes they've altered, just not the unaltered genes themselves. What will be legally considered "altered" isn't clear.

Isolating a portion of a gene from its surrounding material is a complex process, and it does yield something that doesn't occur in nature, said Gary Connell, a biotech patent specialist with Sheridan Ross.

"It's something different than what you and I are walking around with in our bodies," Connell said, disputing the DOJ's coal analogy. "Getting to a [genetic] part that has some commercial significance is differ-

ent from pulling a rock out of the ground."

Thousand Oaks, Calif.-based Amgen Inc., the world's largest biotech, grew on the success of its anti-anemia drug Epo-gen, which it produces in bulk in Boulder County. In creating the drug, Amgen patented isolated DNA encoding human erythropoietin, the substance that triggers red blood cell creation.

Amgen, which isn't part of the Myriad case, argues that allowing gene patents has been crucial to the industry and the U.S.'s lead in biotechnology.

"If the rights enjoyed by gene patents were curtailed, the search for breakthrough treatments to combat life-threatening diseases — such as cancer, Alzheimer's, Parkinson's and ALS — would be slowed considerably," Amgen spokesman David Polk said in an email.

The DOJ position and the lower court ruling reflects a stance that's taken hold in gene research circles for a while, said David Allen, vice president of the University of Colorado Technology Transfer Office. The office licenses commercial patents derived from CU research, including many biotechnology patents.

CU long has avoided the kind of patents that would be jeopardized by the Myriad case, instead focusing on patents including a novel use of a gene more than the gene itself, he said.

"We've refused to file around the genes themselves without additional uses," Allen said. "The gene itself may be called out, but it's what that gene does and what you can do around it that is really the meat of the matter."