MedicalXpress

U.S. Supreme Court petitioned to review AMP, et al. lawsuit on gene patents

December 15 2011

The American Civil Liberties Union and the Public Patent Foundation have petitioned the U.S. Supreme Court to hear Association for Molecular Pathology v. U.S. Patent and Trademark Office, a case that challenges the validity of patents on two human genes associated with hereditary breast and ovarian cancer.

The American Civil Liberties Union and the Public Patent Foundation originally filed the lawsuit on behalf of a coalition of professional organizations led by the Association for Molecular Pathology (AMP), and representing over 150,000 physicians and scientists, against licensees and patent holders Myriad Genetics and the University of Utah Research Foundation, as well as the U.S. Patent and Trademark Office. Other plaintiffs included individual physicians and scientists, genetic counselors, women's groups and patients.

The lawsuit argued that as "products of nature", genes are ineligible for patenting under Section 101 of the U.S. Patent Act. In addition, the suit asserted that process claims involving comparison of mutated and normal sequences are also invalid. Finally, the plaintiffs challenged the issuance of the patents on Constitutional grounds, contending that the encumbrances placed by the patents on scientific inquiry and medical care violate Article I, Section 8, Clause 8 and the First Amendment.

In March, 2010 a district court granted summary judgment for the plaintiffs, ruling that human genes and the sequence comparison claims are not patent eligible under Section 101. A divided Court of Appeals

for the Federal Circuit last July reversed in part, holding that the gene sequences at issue are patent eligible as "isolated human DNA." However, the Appeals Court affirmed the lower court's finding of invalidity of the comparison, or correlation, claims as unpatentable mental processes.

The patents granted to Myriad give the company the right to exclude others from sequencing the genes or performing other diagnostic tests on BRCA1 and BRCA2. In effect they grant Myriad a monopoly on both medical and research testing for familial breast and ovarian cancer caused by these genes.

"That pathologists can be excluded from 'looking at' or 'reading' a patient's DNA sequence to characterize or assess the risk for disease is akin to prohibiting a physician from taking a patient's pulse to see if his or her heart is beating," said Mary Steele Williams, Executive Director of the Association for Molecular Pathology. "I think that the fact that patients can be prevented from accessing the information contained in their DNA would offend most people's conceptions of individual rights and personal liberty."

AMP is optimistic the Supreme Court will follow its precedents that render natural products, natural laws, and natural phenomena ineligible for patent protection. Only by upholding the prohibition on patenting laws of nature can the patent system foster competition and advancement in test development, and thereby usher in the era of personalized medicine.

"Gene patents are a barrier to innovation in molecular testing because they grant monopolies in diagnostic testing for key biologic relationships in inherited diseases and cancer," said Roger D. Klein, MD, JD, AMP Professional Relations Committee Chair. "One cannot invent around gene patents. Excluding medical practitioners from independently

accessing the information contained within the genes of their patients, and the subsequent loss of competition this implies, results in higher test prices, decreased patient access, and diminished innovation in the development of new test methods. The overall effects on patient care are resoundingly negative."

AMP is deeply concerned about potential restrictions on physician and patient access to information that could inform care, and the chilling effect gene patents have on medical research.

"Because information about gene sequences is so fundamental to elucidating the cause, progression and treatment of disease, patent holders can essentially gain ownership of the understanding of some diseases and of certain areas of patient care itself," said Iris Schrijver, AMP President. "Even the possibility of enforcement by a patent holder creates a chilling effect, as pathologist s become reluctant to perform testing procedures that could benefit patients."

Provided by Association for Molecular Pathology