



Association for Molecular Pathology
Promoting Clinical Practice, Basic Research, and Education in Molecular Pathology

9650 Rockville Pike, Bethesda, Maryland 20814

Tel: 301-634-7939 • Fax: 301-634-7990 • Email: amp@asip.org • www.amp.org

Association for Molecular Pathology Joins the American Civil Liberties Union to Challenge the Constitutionality of Gene Patents

Suit charges that Myriad Genetics BRCA1 and BRCA2 patents interfere with the free flow of information and knowledge in violation of the First Amendment and that human genes are "products of nature" that cannot be patented

Washington, DC – May 13, 2009 – The Association for Molecular Pathology (AMP) announced today that it is working with the American Civil Liberties Union (ACLU) and the Public Patent Foundation to bring a lawsuit charging that patents on two human genes associated with breast and ovarian cancer are unconstitutional and should be invalidated. Individuals with certain mutations along these two genes, known as BRCA1 and BRCA2, are at a significantly higher risk for developing hereditary breast and ovarian cancers.

The lawsuit, *Association for Molecular Pathology, et al. v. U.S. Patent and Trademark Office, et al.*, was filed May 12 in U.S. District Court for the Southern District of New York against the U.S. Patent and Trademark Office (PTO) and Myriad Genetics and the University of Utah Research Foundation, which hold the patents on the BRCA genes. The plaintiffs include organizations representing over 150,000 researchers and pathologists, breast cancer and women's health groups, and individual women.

"After careful deliberation, AMP decided to join this suit as a plaintiff and was the first professional association to do so," said Jan A. Nowak, MD, PhD, the president of AMP. "We have done this for a number of reasons, the most compelling of which is that the principle being argued in the case is consistent with our desire to support public policies that we believe are in the best interests of our profession and the patients we serve."

In 2008, AMP adopted a revised Policy Statement on gene patenting and the licensing of intellectual property that urged an end to the practice of granting patents on single genes, sequences of the genome or correlations between genetic variations and biological states. AMP also encouraged groups that currently hold gene patents, including higher educational and research institutions, not to grant exclusive licenses to access those patents.

"This suit is not intended to allege that Myriad is an unethical company. Rather the intent with both the revised Policy Statement and the lawsuit is to address the larger implications of gene patents. We want to prompt changes to the patent system that will resolve what we see as increasingly narrowing options for manufacturers and laboratories to access gene sequence data to develop the tests needed to make molecular medicine a reality," said Dr. Nowak.

The lawsuit charges that gene patents interfere with the free flow of information and knowledge (among researchers, doctors, patients) in violation of the First Amendment, and that patents on

human genes are illegal under patent law because genes are "products of nature" and the PTO never should have granted patents on them.

The PTO has granted thousands of patents on human genes – in fact, estimates are that about 20 percent of the human genome is under patent. A gene patent holder has the right to prevent anyone from studying, testing or even looking at a gene or to greatly limit those who can access the gene through the use of exclusive licensing agreement. As a result, scientific research has been delayed, limited or even shut down due to concerns about gene patents. In the case of the BRCA genes, Myriad's lab is the only place in the country that performs full sequencing of the genes for diagnostic purposes.

"AMP believes gene patents can serve as a disincentive to innovation in molecular testing because they deny access to a vital baseline of genomic information that cannot be invented around," said Dr. Nowak. "Moreover, threat of enforcement from a patent holder and ensuing litigation costs lead to a chilling effect as clinical laboratories and manufacturers are reluctant to develop new tests that could directly benefit patients. That's why this suit is so important."

About AMP

The Association for Molecular Pathology is an international medical professional association dedicated to the advancement, practice, and science of clinical molecular laboratory medicine and translational research based on the applications of molecular biology, genetics and genomics. Through the efforts of an enthusiastic membership from across the United States and around the world, AMP continues to grow in numbers and influence. The organization is divided into the scientific subdivisions of genetics, infectious diseases, hematopathology, and solid tumors. Each subdivision addresses issues, identifies goals, shapes policy, and provides member benefits specific to that particular discipline. The AMP membership includes individuals from academic medical centers, independent laboratories, government, and industry, including physicians, laboratory directors, scientists, medical technologists, and trainees. AMP members populate the majority of clinical molecular diagnostic laboratories in the United States. AMP members are at the forefront of the development and implementation of novel molecular diagnostic tests, whether these are laboratory developed or commercially developed. AMP promotes molecular testing that is consistent with the highest standards established by CLIA, the College of American Pathologists (CAP), the American College of Medical Genetics (ACMG), and FDA. AMP members proudly accept their responsibilities in assessing the analytical validity, clinical validity, clinical utility, and the clinical utilization of molecular tests for each specific patient.

CONTACT:

Rachel Myers, ACLU Media Department
(212) 549-2689
rmyers@aclu.org