



Association for Molecular Pathology

Promoting Clinical Practice, Translational Research, and Education in Molecular Pathology

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FOR IMMEDIATE RELEASE

AMP Appeals Breast Cancer Gene Patent Case to U.S. Supreme Court Case Challenges Patents as Dangerous Roadblock to Patient Care, Medical Innovation

Bethesda, MD, September 26, 2012: The Association for Molecular Pathology (AMP) has petitioned the United States Supreme Court to review the Court of Appeals for the Federal Circuit's (CAFC's) recent ruling in *Association for Molecular Pathology v. U.S. Patent and Trademark Office*, a case that challenges the validity of patents on two human genes, *BRCA1* and *BRCA2*, that predispose women to hereditary breast and ovarian cancer. The American Civil Liberties Union and the Public Patent Foundation filed the appeal to the High Court on behalf of AMP and other medical and professional organizations representing over 150,000 physicians and scientists. Other plaintiffs in the suit include individual physicians and scientists, genetic counselors, women's groups and patients.

After a district court initially declared the *BRCA1* and *BRCA2* patents invalid in March 2010, the CAFC reversed. That decision was appealed to the Supreme Court, which remanded the case to the lower court for further consideration in light of its recent decision in *Mayo v. Prometheus*. In *Mayo*, the Supreme Court found a method patent on another biological relationship was invalid under section 101 of the Patent Act because it claimed an unpatentable natural phenomenon. Upon reconsideration, the CAFC again upheld the patents on the breast cancer genes, claiming that the patentees had invented a new chemical substance through their identification of the disease-causing genetic mutations.

"AMP is now looking to the Supreme Court to correct this wrong on behalf of patients and their at risk family members. Patents on genes such as *BRCA1* and *BRCA2* grant diagnostic test monopolies to commercial companies, which often assemble the genetic knowledge acquired through testing in proprietary databases to which the medical community lacks access," stated Mary Steele Williams, Executive Director of the Association for Molecular Pathology.

Iris Schrijver, MD, President of the Association for Molecular Pathology added, "Gene patents prevent pathologists from reading their patients' DNA sequences to assess their risks for disease, their prognoses, or their potential responsiveness to therapy. The result of this lack of competition is increased test costs; decreased patient access; reduced innovation in the development of new test methods; and dramatically reduced knowledge dissemination."

"The Court of Appeals' decision was disappointing," said Roger D. Klein, MD, JD, Chair of the AMP Professional Relations Committee, "but we are optimistic the High Court will continue to uphold longstanding precedents that prohibit the patenting of natural phenomena. The CAFC's majority opinion failed to acknowledge the reasoning underlying the *Mayo* decision. Further, it took an extremely narrow approach to the question of patent eligibility of the *BRCA1* and *BRCA2* genes, considering only whether there were physical changes to the genes' organizational arrangements, not whether these changes altered their fundamental properties. The essence of DNA is its ability to store the blueprints for human life within its code. The CAFC's decision was analogous", he added, "to treating genes as computer hardware, when their essence is really that of software. In this case, of course, the software code was written by nature, not man."

ABOUT AMP:

The Association for Molecular Pathology (AMP) 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. For more information, please visit www.amp.org.

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