

Association for Molecular Pathology

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FOR IMMEDIATE RELEASE

AMP Optimistic in Suit to invalidate Patents on Breast Cancer Genes

Bethesda, MD, March 27, 2012: Now that the Supreme Court has remanded Association for Molecular Pathology et al. v. Myriad Genetics, Inc., et al. (AMP v. Myriad) to the Court of Appeals for the Federal Circuit for further consideration, AMP is optimistic that it will ultimately prevail in its lawsuit to invalidate patents on two genes that are known to cause breast cancer.

"Our members have witnessed the adverse effects of gene patents on patient care," stated Iris Schrijver, AMP President. "By awarding monopolies in testing of patented genes, these patents reduce patient access to genetic tests, increase test prices, and stand in the way of innovations in diagnostic methods." Further, Dr. Schrijver added, "Because variation in gene sequences plays an important role in the development and progression of many diseases, through gene patents patent holders can essentially gain ownership of the understanding of some diseases and of certain areas of patient care itself."

Stated Roger D. Klein, MD, JD, Chair of the AMP Professional Relations Committee: "We were extremely encouraged by the Supreme Court's reaffirmation in its Prometheus decision of the longstanding principle that natural phenomena are not patent eligible. In Prometheus, the Supreme Court clearly ruled that the correlation between a biomarker and a clinical phenotype cannot be patented. Similarly, in light of this decision we expect that the Court of Appeals for the Federal Circuit will ultimately find that patents on natural products, in this case BRCA1 and BRCA2, cannot be used to exclude physicians and others from examining their patient's genes for disease-related variants."

In its original decision, the Appeals Court held that human gene sequences are patentable subject matter when separated from their native state within cells. This is really a 'form versus substance' argument, said Mary Williams, AMP Executive Director. "A disease-causing mutation means the same thing for the patient irrespective of whether a gene is examined inside or outside the patient's body."

"AMP is looking forward to the proceedings in the lower court. We are confident that optimal patient care and sound science will ultimately prevail," stated Williams.

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 <u>www.amp.org</u>.

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