

Association for Molecular Pathology

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

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FOR IMMEDIATE RELEASE

AMP Applauds Supreme Court Ruling: Sees Win for Patients and Personalized Medicine

Bethesda, MD, March 21, 2012: "The Association for Molecular Pathology (AMP) applauds the U.S. Supreme Court's ruling today in the case of *Mayo Collaborative Services v. Prometheus Laboratories* as a victory for patients and for the advancement of personalized medicine," stated Iris Schrijver, MD, the Organization's President. AMP, an international professional society representing more than 2000 physicians, doctoral scientists, and medical technologists, joined 10 other medical and healthcare organizations in filing an amicus brief with the Court in support of Mayo Clinic. AMP is also the lead plaintiff in *Association for Molecular Pathology v. U.S. Patent and Trademark Office* that challenges the validity of patents on two human genes associated with hereditary breast and ovarian cancer and is currently under review by the High Court.

"Prometheus acknowledged that physicians can infringe the patent by merely thinking about the relationship between drug metabolite levels and patient response," asserted Dr. Schrijver. "It is encouraging that the Court recognized that the Prometheus patents neither promote the advancement of medical practice, nor benefit patient care".

"In Prometheus, the Court wisely recognized that overly broad patents can inhibit innovation," stated Jennifer Hunt, MD, MEd, the Organization's President-Elect. "Establishing a drug reference range is important, but standard work for laboratory physicians. Awarding monopolies over the medical use of natural, biological relationships stifles innovation in true diagnostic test methods and obstructs improvements for patient care."

AMP believes the Supreme Court's reasoning in *Mayo v. Prometheus* extends to patents that claim ownership over another type of natural phenomenon, the biological relationships between genetic variants and clinical disease. Such relationships are at the heart of personalized medicine. "Patients are increasingly being disadvantaged by gene correlation patents," stated Roger D. Klein, MD, JD, Chair of AMP's Professional Relations Committee. As an example, Dr. Klein cited a method patent relating to a variation in a gene known as *FLT3* that is used to qualify some leukemia patients for bone marrow transplant.

Enforcement of the *FLT3* patent by a private company has been forcing physicians and laboratories to split and geographically distribute irreplaceable bone marrow specimens. "Splitting samples creates an additional risk of specimen loss and delays the receipt of patient results" stated Dr. Klein. "In addition, it interferes with the ability of pathologists to provide synoptic interpretations involving multiple tests, and prevents them from implementing cost saving algorithms that limit unnecessary testing. The Supreme Court's ruling is clearly a win both for our patients and for personalized healthcare."

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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