

# AMP presented testimony to the Patent and Trademark Office requesting moratorium on human gene patenting

February 16 2012

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Today, the Association for Molecular Pathology (AMP) asked the U.S. Patent and Trademark Office (USPTO) to place a moratorium on the issuing of patents on human genes during testimony presented at an Agency hearing on genetic diagnostic testing. AMP is the lead plaintiff of 20 plaintiffs in an American Civil Liberties Union (ACLU) sponsored lawsuit challenging the validity of patents on two hereditary breast and ovarian cancer genes, BRCA1 and BRCA2. AMP joined the litigation because of its members' first hand view of the harmful effects of gene patents on patients with genetic diseases and their at-risk family members. "Every day, AMP members witness the ability of genetic testing to better patients' lives and improve their health. Unfortunately, they also experience firsthand the challenges imposed by gene patents that interfere with the practice of medicine and limit their treatment decisions," said Mary Williams, Executive Director of AMP.

AMP believes previous scientific and federal advisory committee publications, and the common knowledge of practitioners in the field, provide ample evidence for the patient harms and negative impact on testing associated with gene patents, and argue against [human genes](#) and genotype-phenotype associations as patentable subject matter. Further, AMP is also concerned that because the USPTO is not a healthcare focused agency it does not possess the needed expertise and resources to adequately assess the impact of patents on patients' ability to obtain confirmatory testing. For these reasons, AMP strongly urges the USPTO

to base its assessment of the impact of gene patents on genetic testing on the report published by the Department of Health and Human Services (HHS) Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) published in April 2010 entitled, "Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests."

Ms. Williams explained, "This almost 400 page report represents approximately four years of active investigation and study and is an important reference on the subject. AMP encourages the USPTO to adopt the recommendations contained in the report."

"Patients are increasingly being harmed by patents that claim ownership over the biological relationships between genetic variants and clinical disease," stated Roger D. Klein, MD JD, Chair of AMP's Professional Relations Committee. For example, 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 is forcing physicians and laboratories to split and geographically distribute irreplaceable bone marrow specimens. "Splitting samples not only creates an additional risk of specimen loss and delays the receipt of patient results," stated Dr. Klein, "it interferes with the ability of pathologists to provide synoptic interpretations involving multiple tests and prevents them from implementing cost saving algorithms that restrict testing to those tests that are truly necessary."

In light of the preceding, AMP asked the USPTO to place a moratorium on issuing gene patents. "By ceasing to grant gene patents, the USPTO would protect patients' access to high quality genetic testing until the issue receives full legal, legislative, and administrative consideration," said Ms. Williams.

## Provided by Association for Molecular Pathology

Citation: AMP presented testimony to the Patent and Trademark Office requesting moratorium on human gene patenting (2012, February 16) retrieved 2 May 2024 from

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