



## Association for Molecular Pathology

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

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### **Association for Molecular Pathology Urges Secretary's Advisory Committee to Give Greater Consideration to the Negative Impact of Gene Patents and Restrictive Licensing Practices on Public Health**

*AMP Comments on Draft Report on Gene Patents and Licensing by the Secretary's Advisory Committee on Genetics, Health and Society*

Washington, DC – May 21, 2009 – The Association for Molecular Pathology today urged the Secretary of Health and Human Services' Advisory Committee on Genetics, Health and Society to more definitively explore the negative impact on public health that derives from gene patents and from exclusive and restrictive licensing practices as part of its draft report, *Gene Patents and Licensing and Their Impact on Patient Access to Genetic Tests*.

In its comments, AMP encouraged the Secretary's Advisory Committee to consider additional case studies that demonstrate this concern, including those for molecular tests associated with Spinal Muscular Atrophy (SMA), the second most common lethal, autosomal recessive disease in Caucasians after cystic fibrosis, and for tests associated with connexin-26 and connexin-30, both associated with childhood hearing loss. These tests are increasingly recommended but in each case they are offered through only a limited number of laboratories due to patents and exclusive licensing practices.

“In considering these issues, it's important to note that molecular tests are not static bodies of knowledge any more than our understanding of the human genome is static,” wrote Jan A Nowak, MD, PhD and President of AMP, in the comment letter. “Rather these tests are constantly evolving as our knowledge of the genome expands. Additional discovery in genomics should lead to the betterment of existing tests and the development of new tests provided those discoveries are available to laboratory professionals. In addition, access to underlying genes is essential to validate the results in existing tests, to in effect, gain a ‘second opinion’ for patients.”

AMP has long been concerned that the US Patent & Trademark Office has granted broad patents on genomic discoveries, including individual genes or mutations, and large numbers of new patent applications are continuously under review. In AMP's experience, patent holders and their exclusive licensees have frequently chosen to monopolize molecular testing by restricting other health care providers and facilities from developing or performing tests covered by these patents and licenses.

In 2008, AMP initiated a review of its own public policy positions on gene patents and the exclusive licensing of genetic discoveries, asking many of the same questions raised by the Secretary's Advisory Committee in the Draft Report. [see [http://www.amp.org/Gov/GenePatentPositionStatement\\_Final\\_Nov2008.pdf](http://www.amp.org/Gov/GenePatentPositionStatement_Final_Nov2008.pdf)] At the conclusion of that process, AMP reaffirmed its belief that molecular test services constitute vital medical procedures. As such, they should be widely available to promote optimal patient care, medical education, and medical research.

Most recently, AMP joined 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. 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. In addition to AMP, the plaintiffs include organizations representing over 150,000 researchers and pathologists, breast cancer and women's health groups, and individual women.

AMP's full comment letter to the Secretary's Advisory Committee can be found at [www.amp.org](http://www.amp.org).

### **About AMP**

The Association for Molecular Pathology is a not-for-profit scientific society dedicated to the advancement, practice, and science of clinical molecular laboratory medicine and translational research based on the applications of genomics and proteomics. AMP was founded in 1995 to provide structure and leadership to the then-emerging field of molecular diagnostics. Through its Council and Committees, AMP pursues topics of importance to those at the forefront of this growing discipline. From the beginning, AMP has worked to develop mechanisms for training and certification in diagnostic molecular pathology. AMP has assumed national visibility with its efforts to shape regulations and policy that influence research and the practice of molecular diagnostics. 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. Members can participate in any or all of these subdivisions. The AMP membership includes individuals from academia, government, and industry, including basic scientists, laboratory directors, medical technologists, and trainees. Through the efforts of an enthusiastic membership from across the United States and around the world, AMP continues to grow in numbers and influence.

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