

Association of Molecular Pathology Urges an End to the Practice of Granting Patents on Single Genes and Gene Sequences in the Human Genome and to Exclusive Licenses to Genetic Discoveries

In newly adopted Position Statement, group also calls for stakeholders to develop more innovative models of intellectual property to encourage innovation and improve patient access to improved molecular tests

WASHINGTON, DC – December 1, 2008 – In a statement delivered today before the Secretary of Health and Human Services' Advisory Committee of Genetics, Health and Society (SACGHS), the Association of Molecular Pathology (AMP) urged an end to the practice of granting patents on single genes, sequences of the genome or correlations between genetic variations and biological states. AMP also encouraged groups that currently hold gene patents, including higher educational and research institutions, not to grant exclusive licenses to access these patents.

This statement reflects AMP's newly adopted Position Statement on Gene Patents and Licensing Practices and comes as the Secretary's Advisory Committee is reviewing a preliminary draft report that addresses questions about whether gene patents and certain licensing practices are affecting patient access to genetic tests.

Debra Leonard, MD, PhD, Vice Chair of Laboratory Medicine and Director of the Clinical Laboratories in the Department for Pathology and Laboratory Medicine at the Weill Cornell Medical College and NewYork-Presbyterian Hospital, as well as a member of AMP's Professional Relations Committee, presented the AMP statement to the SACGHS, which includes the following: "Gene patents can serve as a disincentive to innovation in molecular testing because they deny access to a vital baseline of genomic information that cannot be invented around. Moreover, threat of enforcement from a patent holder and ensuing litigation costs lead to a chilling effect as clinical laboratories are reluctant to develop new tests that could directly benefit patients."

The AMP statement continues, "In addition to the concern about gene patents, exclusive licenses that confine molecular testing to a single provider are detrimental to the public interest by limiting patient access to testing, restricting medical practice and research, impeding the advancement of medical knowledge and enhancement of the public's health through informed clinical decision making." The AMP Position Statement also advocates that financial terms for licenses to genetic discoveries for clinical test development should be reasonable and that "sole source" tests should be prohibited.

Finally, the Position Statement calls on a number of involved stakeholders to work cooperatively to develop alternatives to gene patents and exclusive licenses with the goal of increasing patient access to health care and achieving greater benefit from the existing body of intellectual property linked to the human genome.

This Position Statement marks the first significant re-statement of AMP's policy on Intellectual Property since 1999, according to Jan A. Nowak, PhD, MD, of NorthShore

University HealthSystem's Evanston Hospital and the President of AMP. "AMP has always advocated an open access approach to clinical testing and research, believing it to be in the best interest of both the laboratories and the patients we serve. In this new era of personalized, predictive and pre-emptive health care, modern technology allows us to look across the genome with incredible depth and diversity, giving clinical labs the ability to develop increasingly sophisticated and individualized tests. However, labs can only develop this next generation of tests when they have access to the broadest base of genomic discoveries."

Full text of the Position Statement can be found at 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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