



Association for Molecular Pathology

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

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Association for Molecular Pathology (AMP) Comments Regarding Gene Patents and Licensing Practices

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Reed V. Tuckson, MD
SACGHS Chair
NIH Office of Biotechnology Activities
6705 Rockledge Drive, Suite 750
Bethesda, MD 20892

Dear Dr. Tuckson and Members of the Secretary's Advisory Committee on Genetics, Health and Society:

The Association for Molecular Pathology (AMP) is an international medical professional association representing over 1,400 physicians, doctoral scientists, and medical technologists who perform genetic testing, as well as other testing, based on knowledge derived from molecular biology, genetics, and genomics. AMP members practice their specialty in academic medical centers, community hospitals, independent clinical laboratories, and federal and state health facilities.

On behalf of our membership, The Executive Council and Professional Relations Committee of AMP thank the Committee for the opportunity to provide commentary on the issue of intellectual property rights and patent protection of genetic information.

Many disease-causing genes from humans and their pathogens have been discovered in recent years, and countless more will be discovered in the coming decades. Clinical laboratories develop many of these discoveries into genetic tests and make these tests widely available as clinical services for the public good. In many instances, the U.S. Government has granted extremely broad patents on genetic discoveries, and large numbers of new patent applications presently are submitted or under review. Increasingly, patent holders or their licensees are choosing to monopolize genetic testing by preventing all other health-care providers and facilities from performing tests covered by the patents.

Our members have had to cease, curtail, or alter clinical laboratory testing due to restrictive gene patents for an ever-growing list of diseases, including Alzheimer disease, hemochromatosis, neurodegenerative disorders, congenital deafness, familial breast and ovarian cancer, lymphomas, and treatment-resistant leukemias.

The Association for Molecular Pathology believes that:

- The human genome sequences are in the public domain; therefore, there should be open access to them for any clinical application.
- Genetic test services are medical procedures. As such, they should be widely available to promote optimal patient care, medical education, and medical research.
- Most discoveries of pathogen or human disease genes can be effectively translated into genetic tests without the need for the incentives provided by patents or exclusive license agreements.

- The restrictive use of patents or exorbitant licensing fees prevents physicians and clinical laboratories from performing genetic tests, limits access to medical care, jeopardizes the quality of medical care, and raises its cost.
- The research, development and practice of genetic testing in academic medical centers is essential to medical progress, the education of physicians, researchers and healthcare professionals, and the continued improvement of the quality of medical care.
- Exclusive licenses that limit genetic testing to a single provider are detrimental to the public interest by limiting patient access to testing, medical education and practice, the advancement of medical knowledge, and the enhancement of the public's health.

AMP urges the Committee to investigate the clinical impact of gene patents and develop recommendations for steps that can be taken so that patients continue to have broad access to the benefits derived from ongoing and future research on the genetic basis of disease. Consequently, AMP makes the following recommendations:

- All clinical laboratories should be exempt from gene patent restrictions for diagnostic testing in the practice of clinical medicine.
- Research funding agencies should oppose patent licensing agreements that inappropriately limit clinical care, the use of medical procedures, medical education, and medical research.
- Organizations (including universities) that hold patents and require licenses for use of their technology for genetic testing should offer nonexclusive licenses and make these available to any qualified, CLIA-certified high-complexity laboratory on an equal basis.
- To ensure that testing remains widely available and affordable, financial terms for test licenses should be reasonable. License agreements should also be free of any terms that limit the number of tests that can be performed by a laboratory or regulate the technical performance or clinical uses of the test. License agreements should likewise be free of terms that inappropriately limit research related to testing or the public dissemination of the resulting research findings.

AMP appreciates the opportunity to address the Committee on this very important topic. We reiterate our commitment to participate not only in assisting the Committee in pursuit of its goals, but in translating the results of those efforts for the betterment of the public's health and well being. Please contact Wayne W. Grody, MD, PhD, Chair of the AMP Professional Relations Committee at wgrody@mednet.ucla.edu if we can provide further information.

Respectfully yours,



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