



The Association for Molecular Pathology
Comments to the Secretary's Advisory Committee on Genetics, Health and Society
February 4, 2010

The Association for Molecular Pathology (AMP) is a nonprofit medical professional association representing approximately 1,800 physicians, doctoral scientists, and medical technologists who perform laboratory testing based on knowledge derived from molecular biology, genetics, and genomics. AMP has long been concerned that the US Patent & Trademark Office has historically granted broad patents on genomic discoveries, including individual genes or mutations. In AMP's experience, an unintended consequence of Bayh-Dole has been that patent holders and their exclusive licensees have frequently chosen to monopolize molecular testing by restricting other health care providers and facilities from developing, performing, and improving tests covered by these patents and licenses. AMP believes that this in many cases restricts access to health care, and in more extreme cases may even endanger patients.

AMP strongly endorses the SACGHS Report *Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests*. AMP commends the Committee for addressing the challenge of DNA patents, for extending its position to association patents, and for taking steps to limit or eliminate exclusive licensing practices. If implemented, the Committee's recommendations would be a significant step forward to reverse years of policy that has hindered innovation, restricted patient access to tests, and constrained the widespread clinical application of biomedical research. AMP urges the Committee to finalize unchanged the recommendations presented last October and to encourage the Secretary and the Administration to act swiftly to implement them in their entirety.

The Committee reached these conclusions after more than three years of careful analysis, sufficient public comment, and stakeholder engagement. In fact, the draft report released in March 2009 was written after the completion of a study initiated by the Committee in 2006 to assess the positive and negative effects of licensing practices on patient access to genetic tests. The research was thorough, reviewed by the full Committee with many opportunities for public comment, and led to a well-researched and documented report.

AMP agrees that attaching intellectual property rights to true acts of invention such as new therapeutics, diagnostics, or technology platforms is essential to encourage investment and reward innovation. A single gene or a sequence of the genome, however, is not only a product of nature, but contains heritable information that should not be patentable. Threats of enforcement from a patent holder and ensuing litigation costs lead to a chilling effect on the availability of genetic testing that could otherwise directly benefit patients, since clinical laboratories are reluctant to develop new tests under the current restrictive environment.

AMP urges the Committee to move expeditiously to finalize the Report as presented last October so these much needed recommendations can be put into practice.