



AMP

ASSOCIATION FOR MOLECULAR PATHOLOGY

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Commissioner of Patents and Trademarks
Box 8
Washington, DC 20231

Attn: Mark Nagumo
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March 17, 2000

Dear Commissioner of Patents and Trademarks,

The Association for Molecular Pathology would like to provide brief comments on the Patent and Trademark Office's (PTO) Revised Interim Utility Examination Guidelines that affect the patentability of genetic sequence data. The Association for Molecular Pathology (AMP) is a society of medical professionals engaged in the practice of laboratory-based human molecular diagnostics and translational research in molecular pathology, molecular medicine, and molecular genetics. Our more than 500 members are primarily M.D. and/or Ph.D. diagnostic laboratory directors or are doing translational research or developmental diagnostics in this field. Therefore, the patenting of genetic sequences is of great concern and interest to our members.

The increased stringency of the new utility requirement, to require documentation by the applicant of specific and substantial utility that is credible, is an improvement from the previous guidelines. The new guidelines will prevent the patenting of sequences, such as expressed sequence tags (ESTs), without knowledge of the function of the encoded protein. This will prevent reach through rights to future patents that do demonstrate function and utility of the same sequence, and potentially limit the stacking of patent licenses required for individuals seeking to use the information for research or medical applications. Therefore, we are pleased with the new guidelines.

However, the new guidelines will not solve the current problem in genetic diagnostics that gene sequence patents are creating, since the molecular diagnostic community uses and will continue to use the gene sequences with clearly demonstrated medical utility. The limitation that genetic sequence patents are placing on the clinical application of this human genome information is not in the public's best interest. While AMP understands that the PTO does not set the laws which govern its practice, we feel strongly that the PTO should understand the restraints that gene patents are placing on the clinical practice of molecular diagnostics.

Thank you for providing us the opportunity to share with you our concerns on this matter.

Sincerely,

Debra G.B. Leonard, M.D., Ph.D.
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