

## **ACLPS Resolution: Exclusive Licenses for Diagnostic Tests**

**Approved by the ACLPS Executive Council, 06/03/99**

### **Background:**

Use of patents and exclusive licenses to limit diagnostic testing Many disease-causing genes have been discovered in recent years. These discoveries are frequently made available to the public in the form of diagnostic genetic tests developed by clinical laboratories and offered as clinical services. In many instances, patents have also been granted for these discoveries. In some cases, the holders or licensees of these patents have sought to monopolize these tests, and are attempting to force all other health-care facilities to stop performing these medical procedures.

For example, Athena Diagnostics has obtained exclusive licenses from universities to perform diagnostic testing for Charcot-Marie-Tooth disease, apolipoprotein E genotyping, and spinocerebellar ataxia type 1, and has forced other clinical laboratories to stop performing these tests. Myriad Genetics has forced clinical laboratories to stop testing for BRCA1 and BRCA2 mutations. SmithKline Beecham recently tried to use an exclusive license agreement to prevent all other laboratories from performing diagnostic testing for hereditary hemochromatosis, and modified this position only under pressure.

### **ACLPS believes that:**

- In vitro diagnostic tests are medical procedures, and as such they should be widely available to promote optimal patient care, medical training, and medical research;
- Most discoveries of human disease genes can be effectively translated into diagnostic in vitro tests without the need for exclusive license agreements;
- When patents are used to prevent physicians and clinical laboratories from performing diagnostic procedures, this can limit access to medical care, jeopardize its quality, and raise its cost;
- The practice of genetic testing in academic medical centers is essential to medical research and the training of physicians and health-care professionals;
- Exclusive licenses on diagnostic procedures can also damage the public interest by interfering with medical training and medical research.

### **ACLPS recommends that:**

- Physicians and scientists should oppose patent licensing agreements that inappropriately limit clinical care, medical training, and medical research;

- Government and non-profit institutions that hold patents controlling in vitro diagnostic testing services should not issue exclusive licenses for these patents unless there is a clear and compelling need for exclusivity in order to make the technology available to the public. Such cases are expected to be extremely rare;
- When patent holders choose to require royalty-bearing licenses for use of their technology for in vitro diagnostic testing, such licenses should be nonexclusive and available to any qualified, CLIA-certified laboratory on an equal basis. Financial terms for such licenses should be reasonable;
- License agreements should be free of any terms that dictate specific methods of testing, methods of reporting results, or clinical uses of the test.

## **Bibliography**

Merz JF. Disease gene patents: overcoming unethical constraints on clinical laboratory medicine. *Clinical Chemistry* 1999; 45:324-330.

Association for Molecular Pathology. Letter to Dr. Francis Collins, November 8, 1998.

Tait JF. Exclusive licenses for home-brew genetic tests. Some questions and answers. Unpublished document of the Department of Laboratory Medicine, University of Washington, December 23, 1998.