College of American Pathologists

Statement to the
Secretary’s Advisory Committee on Genetics, Health and Society
(SACGHS)

March 27-28, 2006
The College of American Pathologists is a national medical specialty society representing more than 16,000 pathologists who practice anatomic pathology and laboratory medicine in laboratories worldwide. The College's Commission on Laboratory Accreditation is responsible for accrediting more than 6,000 laboratories here and abroad. College members have extensive expertise in providing and directing laboratory services and serve as inspectors in the laboratory accreditation program. In addition, the College provides laboratories with a wide variety of proficiency testing programs and educational solutions to assist in the improvement of the laboratory's performance and its positive impact on patient care. Specifically, the College has been a leader in developing quality improvement programs for laboratories, including programs in molecular pathology and cytogenetics.

The National Academy of Sciences (NAS) Science, Technology and Economic Policy (STEP) Board and the Science, Technology, and Law Committee released a much anticipated gene patent study commissioned by the National Institutes of Health entitled “Intellectual Property Rights in Genomic and Proteomic Research: Access to Discoveries, Inventors' Rights, and Public Health.” The College provided testimony to the Committee towards the development of the report and was awaiting the completion of the study and subsequent recommendations. The study recommends that policy-makers take appropriate steps to prevent the increasingly complex web of intellectual property protections from impeding potential breakthroughs in genomic and proteomic research. The report suggests several approaches to improving public access to patented inventions. Specifically, it recommends that Congress consider legislation to exempt research on certain aspects of patented technologies or inventions from patent-infringement liability, with the goal of promoting scientific discovery. The report also recommends that owners of the patented technology behind certain gene-based diagnostic tests should establish procedures that allow other clinicians to validate test results. If these patent holders do not take this step voluntarily, the report suggests that Congress consider, in the interest of public health, whether work to validate such results should be shielded from liability. The
College has supported similar policy recommendations and has previously advocated for legislation in Congress that would extend certain protections to researchers and laboratories. The report falls short, however, in recommending specific protections for physicians and other providers of clinical laboratory services against gene patent infringement enforcement.

We ask the SACGHS to recommend to the HHS Secretary, the Director of the National Institutes of Health, who sponsored the study, and the National Human Genome Research Institute to reject Recommendation 13 of the report. The College and others provided significant information in the development of the study that warrants the need to provide this protection. The support for recommendations to limit the negative impact of gene patents on clinical testing services is outlined in the background information of the study, however, the Committee failed to provide recommendations to address the data gathered. We also, therefore, ask the SACGHS to carefully review the information provided in the report on the clinical impact of gene patents, consider further investigation of this impact, and develop recommendations for the Secretary of HHS to address the growing negative impact of gene patents on clinical testing in the United States.

IMPACT OF GENE PATENTS ON MEDICAL PRACTICE
We are in the midst of a scientific revolution in genetics that promises extraordinary advances in clinical medicine. As the medical specialists in the diagnosis of disease, College members recognize that genetic testing is an area of growth and change for pathology and medical practice in the decades to come. Pathologists therefore have a keen interest in ensuring that gene patents do not restrict the ability of physicians to provide quality diagnostic services to the patients they serve. Gene patents pose a serious threat to medical advancement, medical education, and patient care. Information derived from mapping of the human genome represents a naturally occurring, fundamental level of knowledge, which is not invented by man and should not be patented. When patents are granted, subsequent exclusive license agreements, excessive licensing fees, and other restrictive licensing conditions prevent researchers, physicians and laboratories from providing genetic based clinical testing services. As a consequence, patient access to care
is limited, quality is jeopardized and training of health care providers is restricted. This is particularly true when the United States Patent and Trademark Office grants extremely broad patents on genetic discoveries and all methods for identifying those genetic variants.

The field of Molecular Pathology uses genes and their mutations to predict or diagnose disease in the fetus, the newborn, the child, and the adult. The list of diseases that can now be diagnosed or predicted from gene-based tests is growing rapidly. Physicians and scientists can easily and rapidly translate the fundamental information derived from mapping the human genome into diagnostic genetic tests and use these tests for patient care. Because information about gene sequences is so fundamental to understanding specific diseases, patent holders can essentially gain ownership of diseases through patents. Exclusive or restrictive license agreements on gene-based tests have been used to prevent physicians and clinical laboratories from performing these tests as diagnostic medical procedures.

Patients suffer because diagnostic test services are less readily and affordably accessible. Medical education and research related to laboratory testing also are threatened. In fact, College members have received "cease and desist" notification letters from patent holders or exclusive licensees indicating that continued patient testing would be patent infringement. Examples of diseases where testing has been halted due to patent enforcement include breast cancer, Alzheimer disease, Canavan disease, and Charcot-Marie-Tooth disease. In further support of this point, in a 1998 informal survey of 74 clinical laboratories performing molecular testing Dr. Jon Merz and his colleagues found:

- 25% had received a "cease and desist" letter from a patent holder or licensee preventing them from continuing to perform a clinical test service that they had developed and were offering.
- 48% had decided not to develop or perform a test for clinical or research purposes, and gave patent restrictions as one of the reasons.
Thousands of gene patents have been granted and over 10,000 patents are pending. Physicians should not be further restricted from medical practice and providing quality care.

HISTORY OF MEDICAL ADVANCES AND PATENTS
Throughout history, medical discoveries have progressed from the discovery of basic anatomy to histology and cytology, none of which are patented, to the more recent discovery of genes. The recent trend of using patents to monopolize gene-based testing services is a radical departure from historical precedent in clinical laboratories, and it works against the goal of making these procedures widely accessible and affordable to the public. Especially troubling is the fact that under patent protection, the increasing understanding of the utility of the test, as well as the underlying disease processes, also becomes proprietary, thereby imposing a profound change in how the profession and the public acquire knowledge about these rapidly evolving tests, the diseases diagnosed by the tests and their clinical utility.

The United States Constitution states that the purpose of the patent system is "to promote the progress of science and useful arts." Patents promote medical progress when they assist the development and broad application of medical advances. A typical example is the development of new drugs: private industry undertakes a large and risky investment in developing new drugs and seeking FDA approval for their marketing. The public benefits when a new FDA-approved drug is made available to all patients and all physicians. Because the human genome is a product of nature, identifying human genome sequence variations associated with disease is not comparable to the invention of a new product such as a new therapeutic drug. Gene-based diagnostic test services can usually be developed directly from the knowledge of the underlying gene-sequence. Development of such diagnostic tests, as compared to developing therapeutic drugs, requires less time and investment. Thus, patents or exclusive licenses are rarely required as inducements to encourage diagnostic test services to be made readily available to patients and physicians, and in some cases impeded the wide dissemination and use of a test.
NEED FOR PROTECTION AGAINST PATENT INFRINGEMENT

For more than a century, medical and surgical methods and processes for diagnosing and treating disease were not considered patentable. In 1952, Congress amended the patent law, adding to the list of subject matter that could be patented "new and useful processes." Since 1952, the patent office has routinely issued method or process patents for purely medical and surgical procedures not associated with any drug or medical device. As many as one hundred of these medical procedure patents are issued each month. Examples include patents granted on a method for cataract surgery or a patent granted on an orthopedic surgery technique. Until recently, such patents were rarely enforced. However, over the past decade, the holders of some of these medical procedure patents actively have sought to enforce them.

In 1996, Congress recognized that medical procedure patents might impede the advancement of medicine, curtail academic access, place unreasonable limits on the research community, and interfere with medical education and the quality of care provided to the patient. As a result, in October 1996, legislation was signed into law (Frist-Ganske Amendment, 35 USC Sec. 287) that permanently precludes the filing of infringement suits against physicians and other medical practitioners for the performance of "medical activities" that would otherwise violate patents on medical or surgical procedures. A "medical activity" is broadly defined to include the performance of a medical or surgical procedure on a human body, organ or cadaver or on an animal used in medical research. However, the law specifically excludes biotechnology patents and clinical laboratory services. With the advent of new and innovative approaches to gene based diagnostic testing, and the promise of enhanced and expanded diagnostic testing, laboratory services and clinicians should have the same protection from patent infringement as other medical providers and procedures.

SUMMARY

We are facing the unprecedented situation in which a single patent owner can prevent physicians throughout the country from performing diagnostic procedures that use certain
gene-based tests. This sets an extraordinary and dangerous precedent for patients and all of medicine, and strays from the constitutional and social purpose of the patent system to promote progress. Therefore, current practices in the patenting and licensing of genetic sequences must be reexamined. The College believes that information derived from mapping of the human genome represents a naturally occurring, fundamental level of knowledge, which is not invented by man and should not be patented, and that gene based diagnostic tests should be widely available and affordable for the greatest public benefit.