College of American Pathologists

Comments to the
Department of Commerce
Patent and Trademark Office
(Docket No. PTO-P-2012-0003)

March 26, 2012

College of American Pathologists
1350 I Street, NW, Suite 590
Washington, DC 20005
(202) 354-7100
(202) 354-7155 – fax
(800) 392-9994
www.cap.org

The College of American Pathologists (CAP), the nation's largest association of Board certified pathologists, appreciates this opportunity to provide comments to the United States Patent and Trademark Office (PTO) on the issue of independent second opinion genetic diagnostic testing. The CAP, *celebrating 50 years as the gold standard in laboratory accreditation,* is a medical society serving more than 17,000 physician members and the global laboratory community. It is the world's largest association composed exclusively of board-certified pathologists and is the worldwide leader in laboratory quality assurance. The College advocates accountable, high-quality, and cost-effective patient care. CAP Laboratory Accreditation Program is responsible for accrediting more than 7,000 clinical laboratories worldwide. Our members have extensive expertise in providing and directing laboratory services and also serve as inspectors in the CMS-deemed CAP accreditation program. CAP also provides laboratories with a wide variety of proficiency testing programs and has the responsibility to evaluate the accuracy of test performance and interpretation in more than 23,000 laboratories worldwide.

Pathologists play an integral role in health care as physicians who obtain and interpret data as the result of examination of tissues, blood, and other body fluids for diagnosis and patient care. The mission of the College is to represent the interests of patients, the public, and pathologists by fostering excellence in the practice of pathology and laboratory medicine worldwide. Therefore, the CAP believes gene patents restrictions on genetic testing infringe on the practice of medicine which impacts the quality of test results including limiting the availability of independent, second opinion diagnostic testing.

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 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 for 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.

IMPACT OF GENE PATENTS ON MEDICINE AND HEALTH CARE

The current scientific revolution in genetics promises extraordinary advances in clinical medicine. As the medical specialists in the diagnosis of disease, pathologists recognize that genetic testing is an area of growth and change for pathology and medical practice now and in the decades to come. The research, development, and practice of genetic testing in academic and other medical centers is essential to medical progress, the training of physicians, researchers and health-care professionals, and the continued improvement of the quality of medical care. Most discoveries of human or pathogen genes can be effectively translated into gene-based diagnostic test services without the incentives provided by patents or exclusive license agreements. 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.

Pathologists have a long track record of delivering high quality services to patients through the practice of laboratory medicine, and have demonstrated through the introduction of thousands of laboratory tests used daily in clinical practice that the best interest of their patients is the primary driver of innovation in laboratory testing. Rather than intellectual property, for pathologists, clinical need, often manifested by requests from clinical colleagues, spurs novel developments in medical testing. We need only turn to the H1N1 epidemic a few years ago to see this principle in practice. Pathologists and their colleagues were able to use the H1N1 sequence information to rapidly develop a molecular test to identify patients infected with this new flu virus. Patents on the H1N1 sequence, if enforced, would

have obstructed these efforts, and valuable time would have been lost negotiating licenses, assuming such licenses could even be obtained at reasonable terms.

Gene patents pose a serious threat to medical advancement, medical education, and patient care. When patents are granted, subsequent exclusive license agreements, excessive licensing fees, and other restrictive licensing conditions prevent physicians and laboratories from providing genetic-based clinical testing services. Gene patents, unlike patents on methods, cannot be "invented-around" as the gene is often explicitly linked to a particular disease; therefore the sharing of information that accompanies patents cannot produce the desired result of innovation. As a consequence, patient access to care is limited, quality of patient care is jeopardized, clinical observations as the basis for new discoveries are compromised, and training of health care providers is restricted.

INDEPENDENT SECOND OPINIONS

The College believes patients should be empowered and able to obtain information about pathology results including second opinions. Exclusive or restrictive license agreements on gene-based tests have been used to prevent physicians and clinical laboratories from performing genetic tests as diagnostic medical procedures. Patients suffer because diagnostic test services are less readily and affordably accessible. For second opinions, this factor provides a greater barrier since patents curtail the availability of clinical information which is needed to correlate the independent second diagnosis with the primary diagnosis.

The quality of clinical laboratory testing rests on the ability of laboratories to replicate each other's measurements and evaluations, formally through the proficiency testing and accreditation programs such as CAP, and informally for each individual patient, through second opinion. The rendering of second opinion benefits from access to clinical outcomes information as well as the understanding of diseases as they evolved over time. On most laboratory tests, independent second opinions are easily obtained. Peer reviewed evidence is the basis for information that pathologists use to render second opinions. Any restrictions on that ability will diminish the quality of medical care and imperil patients. To restrict a patient's ability to evaluate and understand their own genetic makeup is the ultimate depersonalization of medicine. Utilization of genetic tests should be driven solely by peer reviewed clinical evidence.

CONCLUSION

The College believes that gene patents pose a serious threat to medical advancement, medical education, and patient care. Unlike most independent second opinions that are rendered today, patented genetic tests would have a difficult time obtaining an independent second opinion. Please don't hesitate to contact Fay Shamanski, CAP Assistant Director, Economic and Regulatory Affairs at fshaman@cap.org if you have any questions on these comments.