COLLEGE of AMERICAN PATHOLOGISTS

June 25, 2019

Senator Chris Coons
218 Russell Senate Office Building
Washington D.C., 20510

Senator Thom Tillis
113 Dirksen Senate Office Building
Washington D.C., 20510

Representative Doug Collins
1504 Longworth House Office Building
Washington D.C., 20515

Representative Hank Johnson
2240 Rayburn House Office Building
Washington D.C., 20515

Representative Steve Stivers
2234 Rayburn House Office Building
Washington D.C., 20515

Dear Sens. Coons and Tillis, and Reps. Collins, Johnson and Stivers:

On behalf of the College of American Pathologists (CAP), I write to express our opposition to the recent proposal amending Section 101 of the Patent Act. It is the CAP's view that the draft legislation, if enacted, would permit patenting of human genes and naturally occurring associations between genes and disease. It would also create barriers to patients' access to lifesaving genomic tests, eliminate access to confirmatory testing and substantially increase costs of tests that otherwise have benefited from recent advances in technology that have reduced costs and expanded access for patients. Further, the legislation would eliminate the judicially created exceptions to patent-eligibility thereby overturning the *Mayo, Myriad,* and *Alice* decisions.

As the world's largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs, the College of American Pathologists (CAP) serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide. Pathologists recognize that genetic testing is an area of growth and change for pathology and medical practice. Pathologists therefore have a vested interest in ensuring that legislation does not restrict the ability of physicians to provide quality diagnostic services to the patients they serve.

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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. Until the Court's Myriad decision, a woman could find out if she carried the mutated gene only from a test provided by Myriad at a cost of more than $3,000. The Court's decision opened the door for other companies and researchers to create their own tests and conduct their own research on the previously patented genes. Now there are tests for BRCA1 and BRCA2 as well as 72 other genetic tests for as little as $249. Sec 101, as drafted, threatens over a century of precedent. Peer-reviewed evidence is the basis for information that pathologists use to render primary diagnoses and second opinions. Gene based diagnostic tests must be made widely available and affordable for the greatest public benefit.

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 being able to provide genetic-based clinical testing services. Therefore, patient access to care is limited, quality of patient care is jeopardized, clinical observations which serve as the basis for new discoveries are compromised, and the training of health care providers is limited. These issues were of importance in the *Myriad* case. In that case, the patents granted to Myriad gave it a monopoly over the *BRCA 1* and *BRCA 2* genes. As a result, Myriad shut down genetic testing performed by other laboratories, which meant patients did have not access to confirmatory testing that would ensure the accuracy of the initial diagnosis they received. Myriad also prevented other laboratories from providing more comprehensive testing of the genes and gene mutations that were correlated to high risk for breast cancer and ovarian cancer – resulting in many patients receiving false negative results.

Patients should be empowered and able to obtain information about their own pathology test results, including second opinions on genetic or other clinical tests and interpretations. Unlike most independent second opinions for diagnostic tests that are rendered today, patients would have a difficult time obtaining an independent second opinion on a genetic test protected by a gene patent because no laboratory would be able to develop and perform a genetic test for confirmatory testing purposes. As a result, very important second opinion genetic testing would not be provided by clinical laboratories, if routine primary testing also is not possible due to gene patents.

Pathologists 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 exclusive or restrictive license agreements on gene-based tests, which have been used to prevent physicians and clinical laboratories from performing genetic tests as diagnostic medical procedures. CAP members have, in the past, 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, beside *BRCA,* include Alzheimer disease, Canavan disease, and Charcot-Marie-Tooth disease.

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To restrict a patient's ability to evaluate and understand their own genetic makeup is the ultimate depersonalization of medicine. As you move forward, the CAP urges you to amend the draft legislation to address these concerns. The CAP appreciates the opportunity to provide comments on Sec. 101. Please contact Darren Fenwick at dfenwic@cap.org if you have additional questions or comments.

Sincerely,

R. Bruce Williams, MD

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President
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