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July 12, 2013

Doctor Francis S. Collins, M.D., Ph.D  
Director, National Institutes of Health  
United States Department of Health and Human Services  
9000 Rockville Pike  
Bethesda, Maryland 20892

Dear Doctor Collins:

I write to urge you to consider using march-in rights under the Bayh-Dole Act to ensure greater access to genetic testing for breast and ovarian cancer.

Early genetic testing for markers that indicate an elevated risk of breast cancer and ovarian cancer can save lives and reduce healthcare costs. Myriad Genetics has developed a test for which it has testified that, if a woman tests positive, she has up to an 87 percent risk of developing breast cancer and up to a 44 percent risk of developing ovarian cancer. According to Myriad's testimony, pre-symptomatic individuals who test positive can reduce their risk of developing these cancers by more than 50 percent.

Myriad's genetic test, which was developed with federally-funded research, is truly important for public health. Myriad is the only provider of this test because it is covered by patent protection. Unfortunately, testimony before the United States Patent and Trademark (USPTO) revealed that Myriad does all of this testing in-house, and charges between \$3,000 and \$4,000. The American Society for Clinical Pathology testified that "[m]illions of women are potentially affected by either of these mutations [that indicate an increased risk for breast or ovarian cancer], and for many of them this test at that price is simply cost-prohibitive."

Last month, the Supreme Court announced its decision in *Association for Molecular Pathology v. Myriad Genetics, Inc.* The Court's unanimous opinion held that Myriad's patent claims on isolated deoxyribonucleic acid (DNA) do not cover patent eligible subject matter, but that the claims to complementary DNA (cDNA) are patentable. As a result, Myriad may continue to be the only company able to provide women with the genetic testing they need to make important health care decisions.

Myriad's patents were based in part on federally-funded research. Federally-funded research is playing an increasingly important role in our patent system. The Bayh-Dole Act encourages the commercialization of inventions created with federal funds by permitting the recipient to take title to the inventions, generally without reimbursing the government.

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But the Bayh-Dole Act also gives the government tools, known as “march-in rights,” to provide greater access to the subject invention in appropriate situations. The government can require the patent holder to grant a license to the patent on reasonable terms. If the patent owner refuses, the government can directly license the patent in limited circumstances, including if it “is necessary to alleviate health or safety needs which are not reasonably satisfied” by the patentee.

The health benefits of genetic testing for breast and ovarian cancer are clear. The healthcare cost savings are equally clear. I am concerned, however, that the health needs of the public are not reasonably satisfied by the patentee in this situation because testimony presented to the USPTO made clear that many women are not able to afford the testing provided by Myriad. I encourage you to consider using your march-in rights in this situation.

Thank you for your consideration.

Sincerely,

A handwritten signature in black ink that reads "Patrick Leahy". The signature is written in a cursive, flowing style. Below the signature is a horizontal line.

PATRICK LEAHY  
Chairman

cc: Hon. Kathleen Sebelius