Says Patent System Being Abused; Defendant Charging $3,000 or more for Breast Cancer Test

WASHINGTON – Congresswoman Louise Slaughter (NY-28), Ranking Member of the House Rules Committee and the only microbiologist in Congress, today sent a letter urging Solicitor General Donald Verrilli to call upon the Supreme Court to hear a potentially landmark gene patenting case.

In a 2-1 decision this past July, a federal appeals court ruled that genes can be patented, overturning a previous lower court decision in The Association for Molecular Pathology v. Myriad Genetics, Inc. In the letter urging Supreme Court consideration, Slaughter, the author of the Genetic Information Nondiscrimination Act (GINA), opposes that decision, saying that gene patenting holds back medical breakthroughs and is fundamentally at odds with the purpose of the US Patent and Trademark Office.

"We cannot reap the full benefits of personalized medicine if researchers must each time go to patent holders in order to analyze a patient's DNA," wrote Slaughter. "The patent system was designed to encourage and reward innovation by protecting the rights of inventors. This system was not meant to cover parts of the human body or the natural world."

Slaughter argued that the gene patenting has been particularly harmful to women. Myriad Genetics, which holds patents on genes called BRCA1 and BRCA2, has a monopoly due to its patent and charges $3,000 or more for its breast cancer risk test.

"We're sitting on the edge of countless scientific breakthroughs and letting the patenting of genes get in the way of saving lives. That's just preposterous to me," said Slaughter. "And what's worse is that not only are we slowing down research with all of these legal loopholes, we're allowing companies to create monopolies and charge patients obscene amounts of money for a test that could save their lives. We need a ruling from the Supreme Court and the help of Solicitor General so we can unleash the ingenuity that will move science forward."

Slaughter has been a longtime advocate of genetic information freedom. In 2008, GINA, legislation that she championed for 13 years, was signed into law. This groundbreaking law,

considered the first civil rights legislation of the 21st Century, prevents health insurers from canceling, denying, refusing to renew, or changing the terms or premiums of coverage based solely on a genetic predisposition toward a specific disease. The law also bars employers from using an individual's genetic information when making hiring, firing, promotion, and other employment-related decisions.

For more on GINA, click here .

For a copy of the letter, click here .

Her full letter is below.

December 6, 2011

Donald B. Verrilli, Jr.

Solicitor General of the United States

U.S. Department of Justice

950 Pennsylvania Avenue, NW

Washington, DC 20530-0001

Dear Solicitor General Verrilli:

Re: The Association for Molecular Pathology, et al. v. Myriad Genetics, Inc., et al., Federal Circuit Docket No. 2010-1406

I am writing with regard to the case challenging patents on the BRCA1 and BRCA2 genes held by Myriad Genetics. While I recognize that the Department of Justice is reluctant to advance its views on cases in which the United States is not a direct party, United States involvement in granting the patents, followed by participation in the Federal Circuit in arguing against the validity of these same patents, make this an exceptional case. Therefore, I urge you to ask the Supreme Court to grant the original plaintiffs' forthcoming petition for writ of certiorari in order to address the questions raised by the decision of the United States Appeals Court for the Federal Circuit.

The sequencing of the human genome was the most momentous medical achievement in this century, with unparalleled implications for public health and personalized medicine. As a result, American innovation in genetic testing is redefining cancer treatment. Genetic tests now exist for 1,500 diseases – hundreds of which are used in cancer care. As we have learned over the years, disease is often the result of complex interactions of many different genes. Dr. Stieglitz, Nobel Prize winning economist, has said that, "Our genetic makeup is far too complicated for a single entity to hold the keys to any given gene and to be able to choose when, if ever, to share." We cannot reap the full benefits of personalized medicine if researchers must each time go to patent holders in order to analyze a patient's DNA. Unfortunately, the U.S. Patent and Trademark Office has been issuing patents on genetic material for decades, and currently twenty percent of our genes have already been claimed as intellectual property.

The patent system was designed to encourage and reward innovation by protecting the rights of inventors. This system was not meant to cover parts of the human body or the natural world. The opposition may say that genes isolated in a test tube are not the same as genes found in the human body. Yet these genes share the same genetic sequence and encode for the same proteins. As the Department of Justice has clearly stated,

"...the unique chain of chemical base pairs that induces a human cell to express a BRCA protein is not a 'human-made invention.' Nor is the fact that particular natural mutations in that unique chain increase a woman's chance of contracting breast or ovarian cancer. Indeed, the relationship between a naturally occurring nucleotide sequence and the molecule it expresses in a human cell – that is, the relationship between genotype and phenotype – is simply a law of nature. The chemical structure of native human genes is a product of nature, and it is no less a

product of nature when that structure is 'isolated' from its natural environment than are cotton fibers that have been separated from cotton seeds or coal that has been extracted from the earth."

The Myriad Genetics monopoly on BRCA1 and BRCA2 clinical diagnosis leads to significant disadvantages for patients, particularly women. When a genetic diagnostic test is offered by only one laboratory, patients do not have an opportunity for a second opinion. Without competition there is little assurance that Myriad will continue to update its test in a timely manner or that it will offer this test at a reasonable price. As a result, Myriad has dictated the standards for breast cancer genetic testing, which has limited patient care and genetic counseling – an unacceptable restriction to place on women seeking medical attention.

Congress intended for Section 101 of Title 35 U.S. Code to stand as a threshold test of patentability, making Court review particularly appropriate in this case. While gene patent proponents often cite Diamond v. Chakrabarty for the proposition that "anything under the sun that is made by man" is patentable, 447 U.S. 303, 309 (1980), that phrase is a misleading quotation from the legislative history of the Patent Act of 1952. The full quote clearly acknowledges the statutory limitations to patentable subject matter: "A person may have 'invented' a machine or a manufacture, which may include anything under the sun made by man, but it is not necessarily patentable under section 101 unless the conditions of the title are fulfilled." H.R.Rep. No.1923, 82d Cong., 2d Sess. 6 (1952). In passing the Patent Act of 1952, Congress reaffirmed that Section 101 would continue to limit the scope of what is considered a true invention by prohibiting the patenting of products of nature, as already established by the Court in cases such as Funk Brothers Seed Co. v. Kalo Inoculant Co., 333 U.S. 127 (1948), and American Fruit Growers v. Brogdex Co., 283 U.S. 1 (1931).

In March, 2010, in the case, In Association for Molecular Pathology, et al v. United States Patent and Trademark Office, et al, Judge Robert W. Sweet, U.S. District Court for the Southern District of New York, ruled that the Myriad patents on BRCA1 and BRCA2 were invalid. In contrast, the Court of Appeals for the Federal Circuit, said that Myriad Genetics is entitled to these patents, but also ruled that Myriad's patent on mutation analysis was not patentable. Judicial conflict on such an important legal and medical issue deserves resolution. The significant and directly contrary positions taken within the administration on the part of the Department of Commerce and the Department of Justice further support the need to seek an authoritative final opinion of the Supreme Court.

In 1995, I introduced legislation called the Genetic Information Nondiscrimination Act (GINA), considered the first civil rights legislation of the 21st Century, which helped open the door to

personalized medicine. By passing GINA in 2008, the U.S. Congress showed itself to be at the forefront of genetics policy. I expect no less of our government when it comes to gene patenting. A decision by the Supreme Court will help clarify the role of Congress and determine if there is a need for congressional directive. Intellectual freedom is critically important for the advancement of science for the good of public health. Therefore, I urge the Solicitor General to join the American Civil Liberties Union, the Public Patent Foundation, and the researchers, genetic counselors, women patients, cancer survivors, breast cancer and women's health groups, and scientific associations, including 150,000 geneticists, pathologists, and laboratory professionals they represent in asking the Supreme Court to grant their petition for writ certiorari.

Sincerely,

Louise M. Slaughter

MEMBER OF CONGRESS