To require the Director of the United States Patent and Trademark Office to conduct a study on effective ways to provide confirming genetic diagnostic test activity where gene patents and exclusive licensing exist, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JUNE 22, 2011

Ms. WASSERMAN SCHULTZ introduced the following bill; which was referred to the Committee on the Judiciary, and in addition to the Committee on Energy and Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To require the Director of the United States Patent and Trademark Office to conduct a study on effective ways to provide confirming genetic diagnostic test activity where gene patents and exclusive licensing exist, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. STUDY ON GENETIC TESTING.

(a) IN GENERAL.—The Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office (in this section re-
ferred to as the “Director” shall conduct a study on effective ways to provide independent, confirming genetic diagnostic test activity where gene patents and exclusive licensing for primary genetic diagnostic tests exist.

(b) Items Included in Study.—The study shall include an examination of at least the following:

(1) The impact that the current lack of independent second opinion testing has had on the ability to provide the highest level of medical care to patients and recipients of genetic diagnostic testing, and on inhibiting innovation to existing testing and diagnoses.

(2) The effect that providing independent second opinion genetic diagnostic testing would have on the existing patent and license holders of an exclusive genetic test.

(3) The impact that current exclusive licensing and patents on genetic testing activity has on the practice of medicine, including but not limited to the interpretation of testing results and performance of testing procedures.

(4) The role that cost and insurance coverage have on access to and provision of genetic diagnostic tests.
(c) Confirming Genetic Diagnostic Test Activity Defined.—For purposes of this section, the term “confirming genetic diagnostic test activity” means the performance of a genetic diagnostic test, by a genetic diagnostic test provider, on an individual solely for the purpose of providing the individual with an independent confirmation of results obtained from another test provider’s prior performance of the test on the individual.

(d) Report.—Not later than 9 months after the date of the enactment of this Act, the Director shall report to the Committee on the Judiciary of the Senate and the Committee on the Judiciary of the House of Representatives on the findings of the study and provide recommendations for establishing the availability of such independent confirming genetic diagnostic test activity.