

112TH CONGRESS
1ST SESSION

H. R. 2276

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. STUDY ON GENETIC TESTING.**

4 (a) IN GENERAL.—The Under Secretary of Com-
5 merce for Intellectual Property and Director of the United
6 States Patent and Trademark Office (in this section re-

1 ferred to as the “Director”) shall conduct a study on effec-
2 tive ways to provide independent, confirming genetic diag-
3 nostic test activity where gene patents and exclusive li-
4 censing for primary genetic diagnostic tests exist.

5 (b) ITEMS INCLUDED IN STUDY.—The study shall in-
6 clude an examination of at least the following:

7 (1) The impact that the current lack of inde-
8 pendent second opinion testing has had on the abil-
9 ity to provide the highest level of medical care to pa-
10 tients and recipients of genetic diagnostic testing,
11 and on inhibiting innovation to existing testing and
12 diagnoses.

13 (2) The effect that providing independent sec-
14 ond opinion genetic diagnostic testing would have on
15 the existing patent and license holders of an exclu-
16 sive genetic test.

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

22 (4) The role that cost and insurance coverage
23 have on access to and provision of genetic diagnostic
24 tests.

1 (c) CONFIRMING GENETIC DIAGNOSTIC TEST ACTIV-
2 ITY DEFINED.—For purposes of this section, the term
3 “confirming genetic diagnostic test activity” means the
4 performance of a genetic diagnostic test, by a genetic diag-
5 nostic test provider, on an individual solely for the purpose
6 of providing the individual with an independent confirma-
7 tion of results obtained from another test provider’s prior
8 performance of the test on the individual.

9 (d) REPORT.—Not later than 9 months after the date
10 of the enactment of this Act, the Director shall report to
11 the Committee on the Judiciary of the Senate and the
12 Committee on the Judiciary of the House of Representa-
13 tives on the findings of the study and provide rec-
14 ommendations for establishing the availability of such
15 independent confirming genetic diagnostic test activity.

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