AMENDMENT TO H.R. 1249, AS REPORTED
OFFERED BY MR. SMITH OF TEXAS

Page 3, line 5, strike “America Invents Act” and insert “Leahy-Smith America Invents Act”.

Page 4, lines 10 and 22, strike “5(a)(1)” and insert “5(a)”.  

Page 16, line 1, insert after the period the following: “In appropriate circumstances, the Patent Trial and Appeal Board may correct the naming of the inventor in any application or patent at issue.”. 

Page 25, strike line 13 and all that follows through page 27, line 2, and redesignate the succeeding subsections accordingly.

Page 27, line 4, strike “registration”.  

Page 27, line 5, strike “inventor to use” and insert “to invent”. 

Page 27, line 6, insert “and the useful arts” after “science”. 

Page 27, line 9, strike “granted by the” and insert “provided by the grant of”.
Page 27, line 12, strike “registration”.

Page 27, line 13, strike “inventor to use” and insert “to invent”.

Page 27, lines 14 and 15, strike “harmonize the United States patent registration system with the patent registration systems” and insert “improve the United States patent system and promote harmonization of the United States patent system with the patent systems”.

Page 27, line 18, strike “a greater sense of” and insert “greater”.

Page 36, strike line 10 and all that follows through page 40, line 5, and insert the following (and conform the table of contents) accordingly:

SEC. 5. DEFENSE TO INFRINGEMENT BASED ON PRIOR COMMERCIAL USE.

(a) IN GENERAL.—Section 273 of title 35, United States Code, is amended to read as follows:

“§ 273. Defense to infringement based on prior commercial use

“(a) IN GENERAL.—A person shall be entitled to a defense under section 282(b) with respect to subject matter consisting of a process, or consisting of a machine, manufacture, or composition of matter used in a manufacturing or other commercial process, that would otherwise
infringe a claimed invention being asserted against the
person if—

“(1) such person, acting in good faith, commerci-
cially used the subject matter in the United States,
either in connection with an internal commercial use
or an actual arm’s length sale or other arm’s length
commercial transfer of a useful end result of such
commercial use; and

“(2) such commercial use occurred at least 1
year before the earlier of either—

“(A) the effective filing date of the claimed
invention; or

“(B) the date on which the claimed inven-
tion was disclosed to the public in a manner
that qualified for the exception from prior art
under section 102(b).

“(b) BURDEN OF PROOF.—A person asserting a de-
fense under this section shall have the burden of estab-
lishing the defense by clear and convincing evidence.

“(c) ADDITIONAL COMMERCIAL USES.—

“(1) PREMARKETING REGULATORY REVIEW.—
Subject matter for which commercial marketing or
use is subject to a premarketing regulatory review
period during which the safety or efficacy of the sub-
ject matter is established, including any period speci-
fied in section 156(g), shall be deemed to be commercially used for purposes of subsection (a)(1) during such regulatory review period.

“(2) NONPROFIT LABORATORY USE.—A use of subject matter by a nonprofit research laboratory or other nonprofit entity, such as a university or hospital, for which the public is the intended beneficiary, shall be deemed to be a commercial use for purposes of subsection (a)(1), except that a defense under this section may be asserted pursuant to this paragraph only for continued and noncommercial use by and in the laboratory or other nonprofit entity.

“(d) EXHAUSTION OF RIGHTS.—Notwithstanding subsection (e)(1), the sale or other disposition of a useful end result by a person entitled to assert a defense under this section in connection with a patent with respect to that useful end result shall exhaust the patent owner’s rights under the patent to the extent that such rights would have been exhausted had such sale or other disposition been made by the patent owner.

“(e) LIMITATIONS AND EXCEPTIONS.—

“(1) PERSONAL DEFENSE.—

“(A) IN GENERAL.—A defense under this section may be asserted only by the person who
performed or directed the performance of the
commercial use described in subsection (a), or
by an entity that controls, is controlled by, or
is under common control with such person.

“(B) TRANSFER OF RIGHT.—Except for
any transfer to the patent owner, the right to
assert a defense under this section shall not be
licensed or assigned or transferred to another
person except as an ancillary and subordinate
part of a good-faith assignment or transfer for
other reasons of the entire enterprise or line of
business to which the defense relates.

“(C) RESTRICTION ON SITES.—A defense
under this section, when acquired by a person
as part of an assignment or transfer described
in subparagraph (B), may only be asserted for
uses at sites where the subject matter that
would otherwise infringe a claimed invention is
in use before the later of the effective filing
date of the claimed invention or the date of the
assignment or transfer of such enterprise or
line of business.

“(2) DERIVATION.—A person may not assert a
defense under this section if the subject matter on
which the defense is based was derived from the patentee or persons in privity with the patentee.

“(3) NOT A GENERAL LICENSE.—The defense asserted by a person under this section is not a general license under all claims of the patent at issue, but extends only to the specific subject matter for which it has been established that a commercial use that qualifies under this section occurred, except that the defense shall also extend to variations in the quantity or volume of use of the claimed subject matter, and to improvements in the claimed subject matter that do not infringe additional specifically claimed subject matter of the patent.

“(4) ABANDONMENT OF USE.—A person who has abandoned commercial use (that qualifies under this section) of subject matter may not rely on activities performed before the date of such abandonment in establishing a defense under this section with respect to actions taken on or after the date of such abandonment.

“(5) UNIVERSITY EXCEPTION.—

“(A) IN GENERAL.—A person commercially using subject matter to which subsection (a) applies may not assert a defense under this section if the claimed invention with respect to
which the defense is asserted was, at the time
the invention was made, owned or subject to an
obligation of assignment to either an institution
of higher education (as defined in section
101(a) of the Higher Education Act of 1965
(20 U.S.C. 1001(a)), or a technology transfer
organization whose primary purpose is to facili-
tate the commercialization of technologies devel-
oped by one or more such institutions of higher
education.

“(B) EXCEPTION.—Subparagraph (A)
shall not apply if any of the activities required
to reduce to practice the subject matter of the
claimed invention could not have been under-
taken using funds provided by the Federal Gov-
ernment.

“(f) UNREASONABLE ASSERTION OF DEFENSE.—If
the defense under this section is pleaded by a person who
is found to infringe the patent and who subsequently fails
to demonstrate a reasonable basis for asserting the de-
fense, the court shall find the case exceptional for the pur-
pose of awarding attorney fees under section 285.

“(g) INVALIDITY.—A patent shall not be deemed to
be invalid under section 102 or 103 solely because a de-
fense is raised or established under this section.”.
(b) CONFORMING AMENDMENT.—The item relating to section 273 in the table of sections for chapter 28 of title 35, United States Code, is amended to read as follows:

“273. Defense to infringement based on prior commercial use.”.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to any patent issued on or after the date of the enactment of this Act.

Page 41, line 5, strike “1 year” and insert “9 months”.

Page 42, line 22, strike “commence” and insert “be instituted”.

Page 43, line 24, and page 44, line 1, strike “petitioner, real party in interest, or privy of the petitioner” and insert “petitioner or real party in interest”.

Page 44, lines 3 and 4, strike “petitioner, real party in interest, or privy of the petitioner” and insert “petitioner or real party in interest”.

Page 44, lines 13 and 14, strike “petitioner, real party in interest, or privy of the petitioner” and insert “petitioner or real party in interest”.
Page 44, lines 16 and 17, strike “petitioner, real party in interest, or privy of the petitioner” and insert “petitioner or real party in interest”.

Page 52, line 10, strike “AMENDED OR NEW CLAIM” and insert “INTERVENING RIGHTS”.

Page 54, insert the following after line 10:

(3) TRANSITION.—

(A) IN GENERAL.—Chapter 31 of title 35, United States Code, is amended—

(i) in section 312—

(I) in subsection (a)—

(aa) in the first sentence, by striking “a substantial new question of patentability affecting any claim of the patent concerned is raised by the request,” and inserting “the information presented in the request shows that there is a reasonable likelihood that the requester would prevail with respect to at least 1 of the claims challenged in the request,”; and
(bb) in the second sentence, by striking “The existence of a substantial new question of patentability” and inserting “A showing that there is a reasonable likelihood that the requester would prevail with respect to at least 1 of the claims challenged in the request”; and

(II) in subsection (c), in the second sentence, by striking “no substantial new question of patentability has been raised,” and inserting “the showing required by subsection (a) has not been made,”; and

(ii) in section 313, by striking “a substantial new question of patentability affecting a claim of the patent is raised” and inserting “it has been shown that there is a reasonable likelihood that the requester would prevail with respect to at least 1 of the claims challenged in the request”.

(B) APPLICATION.—The amendments made by this paragraph—
(i) shall take effect on the date of the enactment of this Act; and

(ii) shall apply to requests for inter partes reexamination that are filed on or after such date of enactment, but before the effective date set forth in paragraph (2)(A) of this subsection.

(C) CONTINUED APPLICABILITY OF PRIOR PROVISIONS.—The provisions of chapter 31 of title 35, United States Code, as amended by this paragraph, shall continue to apply to requests for inter partes reexamination that are filed before the effective date set forth in paragraph (2)(A) as if subsection (a) had not been enacted.

Page 54, line 17, strike “patent owner” and insert “owner of a patent”.

Page 54, line 18, strike “of a” and insert “of the”.

Page 55, line 10, strike “1 year” and insert “9 months”.

Page 57, line 3, strike “commence” and insert “be instituted”.

Page 57, line 25, strike “The” and all that follows through “public.” on page 58, line 1.
Page 58, lines 11 and 12, strike “petitioner, real party in interest, or privy of the petitioner” and insert “petitioner or real party in interest”.

Page 58, lines 15 and 16, strike “petitioner, real party in interest, or privy of the petitioner” and insert “petitioner or real party in interest”.

Page 58, line 25 and page 59, line 1, strike “petitioner, real party in interest, or privy of the petitioner” and insert “petitioner or real party in interest”.

Page 59, lines 3 and 4, strike “petitioner, real party in interest, or privy of the petitioner” and insert “petitioner or real party in interest”.

Page 63, line 15, strike “and”.

Page 63, line 23, strike the period and insert “; and”.

Page 63, insert the following after line 23:

“(12) providing the petitioner with at least 1 opportunity to file written comments within a time period established by the Director.”.

Page 66, line 24, strike “AMENDED OR NEW CLAIM” and insert “INTERVENING RIGHTS”.
Page 68, line 10, strike “to any patent that is” and insert “only to patents”.

Page 78, insert the following after line 1 and redesignate the succeeding subsection accordingly:

   (d) CONFORMING AMENDMENTS.—

   (1) ATOMIC ENERGY ACT OF 1954.—Section 152 of the Atomic Energy Act of 1954 (42 U.S.C. 2182) is amended in the third undesignated paragraph—

       (A) by striking “Board of Patent Appeals and Interferences” each place it appears and inserting “Patent Trial and Appeal Board”; and

       (B) by inserting “and derivation” after “established for interference”.

   (2) TITLE 51.—Section 20135 of title 51, United States Code, is amended—

       (A) in subsections (e) and (f), by striking “Board of Patent Appeals and Interferences” each place it appears and inserting “Patent Trial and Appeal Board”; and

       (B) in subsection (e), by inserting “and derivation” after “established for interference”.

Page 86, lines 11 and 12, strike “examination fee for the application” and insert “applicable fee”.

Page 86, line 15, insert “most recently” after “as”.

Page 86, line 22, strike “examination fee for the application” and insert “applicable fee”.

Page 87, line 1, insert “most recently” after “as”.

Page 87, strike line 18 and all that follows through page 88, line 8, and insert the following:

“(d) INSTITUTIONS OF HIGHER EDUCATION.—For purposes of this section, a micro entity shall include an applicant who certifies that—

“(1) the applicant’s employer, from which the applicant obtains the majority of the applicant’s income, is an institution of higher education as defined in section 101(a) of the Higher Education Act of 1965 (20 U.S.C. 1001(a)); or

“(2) the applicant has assigned, granted, conveyed, or is under an obligation by contract or law, to assign, grant, or convey, a license or other ownership interest in the particular applications to such an institution of higher education.

Page 88, line 9, strike “(2) DIRECTOR’S AUTHORITY.—The Director” and insert “(e) DIRECTOR’S AU-
THORITY.—In addition to the limits imposed by this section, the Director”.

Page 88, move the text of lines 9 through 21 2 ems to the left.

Page 88, line 12, strike “subsection” and insert “section”.

Page 88, line 18, strike “paragraph” and insert “subsection”.

Page 89, line 2, strike “a fee” and insert “an additional fee”.

Page 89, line 17, strike “This” and insert “Except as provided in subsection (h), this”.

Page 89, line 22, strike “6-year” and insert “7-year”.

Page 89, add the following after line 23:

(3) PRIOR REGULATIONS NOT AFFECTED.—The termination of authority under this subsection shall not affect any regulations issued under this section before the effective date of such termination or any rulemaking proceeding for the issuance of regulations under this section that is pending on such date.
Page 96, line 15, strike “either” and all that follows through “patent” on line 19 and inserting “by Office personnel”.

Page 98, strike lines 3 through 14.

Page 102, insert the following after line 7 and redesignate the succeeding subsection accordingly:

(i) Public Enterprise Fund Transition Fees.—

   (1) Surcharge.—

      (A) In general.—There shall be a surcharge of 15 percent, rounded by standard arithmetic rules, on all fees charged or authorized by subsections (a), (b), and (d)(1) of section 41, and section 132(b), of title 35, United States Code. Any surcharge imposed under this subsection is, and shall be construed to be, separate from and in addition to any other surcharge imposed under this Act or any other provision of law.

      (B) Deposit of amounts.—Amounts collected pursuant to the surcharge imposed under subparagraph (A) shall be deposited in the United States Patent and Trademark Office Public Enterprise Fund established under section 22(c).
(2) EFFECTIVE DATE AND TERMINATION OF SURCHARGE.—The surcharge imposed under para-
graph (1)—

(A) shall take effect on the date on which
the surcharge under subsection (j) of this sec-
tion expires; and

(B) shall terminate, with respect to a fee
to which paragraph (1)(A) applies, on the effec-
tive date of the setting or adjustment of that
fee pursuant to the exercise of the authority
under section 10 for the first time with respect
to that fee.

(j) APPROPRIATION ACCOUNT TRANSITION FEES.—

(1) SURCHARGE.—

(A) IN GENERAL.—There shall be a sur-
charge of 15 percent, rounded by standard
arithmetic rules, on all fees charged or author-
ized by subsections (a), (b), and (d)(1) of sec-
tion 41, and section 132(b), of title 35, United
States Code. Any surcharge imposed under this
subsection is, and shall be construed to be, sep-
parate from and in addition to any other sur-
charge imposed under this Act or any other
provision of law.
(B) Deposit of Amounts.— Amounts collected pursuant to the surcharge imposed under subparagraph (A) shall be credited to the United States Patent and Trademark Appropriation Account and shall remain available until expended.

(2) Effective Date and Termination of Surcharge.—The surcharge provided for in paragraph (1)—

(A) shall take effect on the date that is 10 days after the date of the enactment of this Act; and

(B) shall terminate on the effective date set forth in section 22(b)(2).

Page 102, strike lines 1 through 7 and insert the following:

(h) Prioritized Examination Fee.—

(1) In general.—

(A) Fee.—

(i) Prioritized Examination Fee.—A fee of $4,800 shall be established for filing a request for prioritized examination of a nonprovisional application for an original utility or plant patent.
(ii) ADDITIONAL FEES.—In addition to the prioritized examination fee under clause (i), the fees due on an application for which prioritized examination is being sought are the filing fees (including any applicable excess claims and application size fees), processing fee, and publication fee for that application.

(B) REGULATIONS; LIMITATIONS.—

(i) REGULATIONS.—The Director may by regulation prescribe conditions for acceptance of a request under subparagraph (A) and a limit on the number of filings for prioritized examination that may be accepted.

(ii) LIMITATION ON CLAIMS.—Until regulations are prescribed under clause (i), no application for which prioritized examination is requested may contain or be amended to contain more than 4 independent claims or more than 30 total claims.

(iii) LIMITATION ON TOTAL NUMBER OF REQUESTS.—The Director may not accept in any fiscal year more than 10,000
requests for prioritization until regulations
are prescribed under this subparagraph
setting another limit.

(2) Reduction in fees for small entities.—The Director shall reduce fees for providing
prioritized examination of nonprovisional applica-
tions for original utility and plant patents by 50 per-
cent for small entities that qualify for reduced fees
under section 41(h)(1) of title 35, United States
Code.

(3) Deposit of fees.—All fees paid under
this subsection shall be credited to the United States
Patent and Trademark Office Appropriation Ac-
count, or (on and after the effective date set forth
in section 22(b)(2)) in the United States Patent and
Trademark Office Public Enterprise Fund estab-
lished under section 22(c)(1), and shall remain avail-
able until expended.

(4) Effective date and termination.—

(A) Effective date.—This subsection
shall take effect on the date that is 10 days
after the date of the enactment of this Act.

(B) Termination.—The fee imposed
under paragraph (1)(A)(i), and the reduced fee
under paragraph (2), shall terminate on the ef-
effective date of the setting or adjustment of the fee under paragraph (1)(A)(i) pursuant to the exercise of the authority under section 10 for the first time with respect to that fee.

Page 102, lines 8 and 9, strike “Except as provided in subsection (h),” and insert “Except as otherwise provided in this section,”.

Page 105, strike lines 1 through 11.

Page 105, add the following after line 25 and redesignate the succeeding subsection accordingly:

“(e) FRAUD.—If the Director becomes aware, during the course of a supplemental examination or reexamination proceeding ordered under this section, that a material fraud on the Office may have been committed in connection with the patent that is the subject of the supplemental examination, then in addition to any other actions the Director is authorized to take, including the cancellation of any claims found to be invalid under section 307 as a result of a reexamination ordered under this section, the Director shall also refer the matter to the Attorney General for such further action as the Attorney General may deem appropriate. Any such referral shall be treated as confidential, shall not be included in the file of the patent, and shall not be disclosed to the public unless the United
States charges a person with a criminal offense in connection with such referral.

Page 111, strike lines 13 through 24 and insert the following:

“(c) The marking of a product, in a manner described in subsection (a), with matter relating to a patent that covered that product but has expired is not a violation of this section.”.

Page 112, line 2, strike “any case that is” and insert “all cases, without exception, that are”.

Page 113, line 13, insert “or privy” after “interest”.

Page 114, lines 15 and 16, strike “The petitioner in a transitional proceeding,” and insert the following: “The petitioner in a transitional proceeding that results in a final written decision under section 328(a) of title 35, United States Code, with respect to a claim in a covered business method patent,”.

Page 114, line 22, strike “a claim in a patent” and insert “the claim”.

Page 114, lines 23-25, strike “a transitional proceeding that resulted in a final decision” and insert “that transitional proceeding”.
Page 115, line 18, strike “10-” and insert “8-”.

Page 120, strike line 17 and all that follows through the matter following line 10 on page 121 and redesignate succeeding subsections accordingly.

Page 121, line 17, strike “In any” and insert “With respect to any”.

Page 121, line 22, insert “, or have their actions consolidated for trial,” after “defendants”.

Page 122, line 9, strike “or trial”.

Page 122, line 10, insert “, or have their actions consolidated for trial,” after “defendants”.

Page 122, line 11, strike the quotation marks and second period.

Page 122, insert the following after line 11:

1 (c) WAIVER.—A party that is an accused infringer may waive the limitations set forth in this section with respect to that party.”.

Page 126, line 13, strike “patent,” and all that follows through the first appearance of “and” on line 17 and insert “a patent,”.

Page 128, insert the following after line 23 and redesignate the succeeding subsection accordingly:
(k) ADDITIONAL TECHNICAL AMENDMENTS.—Sections 155 and 155A of title 35, United States Code, and the items relating to those sections in the table of sections for chapter 14 of such title, are repealed.

Page 131, line 2, strike “after” and insert “on or after”.

Page 132, strike line 22 and all that follows through page 134, line 9, and insert the following:

(d) REPORTS.—

(1) IN GENERAL.—Not later than 60 days after the end of each fiscal year, the Director shall submit to the Committees on Appropriations and the Judiciary of the Senate and the House of Representatives the reports described in paragraph (2).

(2) REPORTS DESCRIBED.—The reports described in this paragraph are the following:

(A) ANNUAL REPORT.—A report that summarizes the activities of the Office during the preceding fiscal year, including—

(i) financial details and staff levels for each major activity of the Office;

(ii) details of any progress in implementing long-term modernization plans of the Office;
(iii) a list of actual patent and trademark fee collections by the Office; and

(iv) the results of the most recent audit carried out under subsection (e).

(B) ANNUAL SPENDING PLAN.—A summary of the operating plan for the Office for the current fiscal year, including—

(i) the planned operating requirements for the Office, with financial details and staff levels with respect to major activities;

(ii) planned progress towards implementing long-term modernization plans of the Office; and

(iii) an estimate of patent and trademark fee collections.

(3) ANNUAL SPENDING PLAN CHANGES.—If, at any time during the fiscal year, the annual operating requirements differ from those provided in the annual spending plan submitted under paragraph (2)(B) by more than 10 percent of either the patent or trademark business expenses, the Director shall—

(A) notify the Committees on Appropriations and the Judiciary of the Senate and
House of Representatives of the changes in the annual spending plan; and

(B) include with the notification a summary of the changes from the original spending plan, a statement of whether current fiscal year fee collections or fees maintained in the operating reserve will be used to cover obligations in excess of the original spending plan, and an updated annual operating plan of the Office in accordance with paragraph (2).

(4) Testimony before Congress.—Upon the request of any Committee to which the reports are submitted under this subsection, the Director shall appear before that Committee and present such testimony as is requested.

Page 134, line 10, strike “(f)” and insert “(e)”.

Page 134, line 14, strike “(g)” and insert “(f)”.

Page 134, line 17, strike the period and insert the following:

, including—

(1) multi-year plans and out-year funding estimates;

(2) operating reserve balances; and

(3) long-term modernization plans of the Office.
Page 134, insert the following after line 17:

(g) EFFECTIVE DATE.—Subsections (c) through (f) shall take effect on the later of—

(1) October 1, 2011; or

(2) the first day of the first fiscal year that begins on or after the date of the enactment of this Act.

Page 137, strike lines 1 through 7 and redesignate the succeeding sections (and conform the table of contents) accordingly.

Page 137, lines 8 and 9, strike “TECHNOLOGIES IMPORTANT TO AMERICAN COMPETITIVENESS” and insert “IMPORTANT TECHNOLOGIES” (and conform the table of contents accordingly).

Page 138, strike lines 1 through 21 and redesignate succeeding sections (and conform the table of contents) accordingly.

Page 139, insert the following after line 12 and redesignate the succeeding sections (and conform the table of contents) accordingly:
SEC. 27. PERMITTING SECOND OPINIONS IN CERTAIN GENETIC DIAGNOSTIC TESTING.

(a) In General.—Section 287 of title 35, United States Code, is amended by adding at the end the following:

“(d) (1) With respect to a genetic diagnostic test provider’s performance of, or offering to perform, a confirming genetic diagnostic test activity that constitutes an infringement of a patent under section 271(a) or (b) of this title, the provisions of sections 281, 283, 284, and 285 of this title shall not apply against the genetic diagnostic test provider with respect to such confirming genetic diagnostic test activity.

“(2) For the purposes of this subsection:

“(A) The term ‘confirming genetic diagnostic test activity’—

“(i) means the performance of a patented 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, where such prior test was performed by, or under license from, the owner of the patent that is infringed by the acts specified in paragraph (1), and where an
independent confirmation of the prior test is not available from another test provider under a license from the patent owner; but “(ii) does not include—

“(I) the performance of a patented genetic diagnostic test on an individual for the purpose of monitoring or reconfirming the individual’s medical or genetic status over time, for therapeutic treatment selection or determining responsiveness to treatment, and for other purposes that require repeated genetic diagnostic testing of the individual;

“(II) the use of a patented machine or article of manufacture in violation of such patent;

“(III) the use of a patented composition of matter that is commercially available to the genetic diagnostic test provider; and

“(IV) the practice of a patented process other than the process of testing claimed in the patent owner’s patent referred to in paragraph (1).
“(B) The term ‘genetic diagnostic test provider’ means any person or entity that performs a confirming genetic diagnostic test activity, and includes a clinical laboratory or other health care entity at which, on behalf of which, or in association with which the confirming genetic diagnostic test activity is conducted, such as a nursing home, hospital, university, medical school, health maintenance organization, group medical practice, or medical clinic.

“(C) The term ‘patented genetic diagnostic test’ means a patented diagnostic method that is specific to the detection of a mutation or a pattern of mutations of one or more particular genes in an individual, as well as the use of a patented composition of matter, or the practice of a patented use of a composition of matter, where such composition of matter is specific to and necessary for the practice of the diagnostic method and is not commercially available to the genetic diagnostic test provider. When performed in the course of a confirming diagnostic test activity, such term is not limited to the particular embodiments of the patented diagnostic method or composition of matter that were practiced by or under authority of the patent owner in providing the prior genetic diagnostic test.
“(D) The term ‘independent confirmation’ is not limited to the replication of the results of a prior genetic diagnostic test, and includes providing the individual with information that is not otherwise available from the provider of such prior test and that affirms, clarifies, disproves, corroborates, or otherwise aids the individual in interpreting the results of such prior test, including in instances where such results were inconclusive.

“(3) The infringer shall have the burden of establishing the limitation on remedies under paragraph (1), including the production of contemporaneous documentary evidence proving, or tending to prove, that the diagnostic test activity meets the definition of a confirming diagnostic test activity under paragraph (2)(A) at the time the confirming diagnostic test activity was performed”.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect on the date of the enactment of this Act and shall apply to confirming diagnostic test activity performed on or after such date.

SEC. 28. PATENT OMBUDSMAN PROGRAM FOR SMALL BUSINESS CONCERNS.

Using available resources, the Director shall establish and maintain in the Office a Patent Ombudsman Program. The duties of the Program’s staff shall include pro-
providing support and services relating to patent filings to small business concerns and independent inventors.

Page 139, insert the following after line 20 and redesignate the succeeding sections (and conform the table of contents) accordingly:

SEC. 30. LIMITATION ON ISSUANCE OF PATENTS.

(a) LIMITATION.—Notwithstanding any other provision of law, no patent may issue on a claim directed to or encompassing a human organism.

(b) EFFECTIVE DATE.—

(1) IN GENERAL.—Subsection (a) shall apply to any application for patent that is pending on, or filed on or after, the date of the enactment of this Act.

(2) PRIOR APPLICATIONS.—Subsection (a) shall not affect the validity of any patent issued on an application to which paragraph (1) does not apply.

SEC. 31. STUDY OF PATENT LITIGATION.

(a) GAO STUDY.—The Comptroller General of the United States shall conduct a study of the consequences of litigation by non-practicing entities, or by patent assertion entities, related to patent claims made under title 35, United States Code, and regulations authorized by that title.
(b) CONTENTS OF STUDY.—The study conducted under this section shall include the following:

(1) The annual volume of litigation described in subsection (a) over the 20-year period ending on the date of the enactment of this Act.

(2) The volume of cases comprising such litigation that are found to be without merit after judicial review.

(3) The impacts of such litigation on the time required to resolve patent claims.

(4) The estimated costs, including the estimated cost of defense, associated with such litigation for patent holders, patent licensors, patent licensees, and inventors, and for users of alternate or competing innovations.

(5) The economic impact of such litigation on the economy of the United States, including the impact on inventors, job creation, employers, employees, and consumers.

(6) The benefit to commerce, if any, supplied by non-practicing entities or patent assertion entities that prosecute such litigation.

(e) REPORT TO CONGRESS.—The Comptroller General shall, not later than the date that is 1 year after the date of the enactment of this Act, submit to the Com-
mittee on the Judiciary of the House of Representatives and the Committee on the Judiciary of the Senate a report on the results of the study required under this section, including recommendations for any changes to laws and regulations that will minimize any negative impact of patient litigation that was the subject of such study.