

**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:

1 **SEC. 5. DEFENSE TO INFRINGEMENT BASED ON PRIOR**
2 **COMMERCIAL USE.**

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

5 **“§ 273. Defense to infringement based on prior com-**
6 **mercial use**

7 “(a) IN GENERAL.—A person shall be entitled to a
8 defense under section 282(b) with respect to subject mat-
9 ter consisting of a process, or consisting of a machine,
10 manufacture, or composition of matter used in a manufac-
11 turing or other commercial process, that would otherwise

1 infringe a claimed invention being asserted against the
2 person if—

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

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

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

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

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

20 “(c) ADDITIONAL COMMERCIAL USES.—

21 “(1) PREMARKETING REGULATORY REVIEW.—
22 Subject matter for which commercial marketing or
23 use is subject to a premarketing regulatory review
24 period during which the safety or efficacy of the sub-
25 ject matter is established, including any period speci-

1 fied in section 156(g), shall be deemed to be com-
2 mercially used for purposes of subsection (a)(1) dur-
3 ing such regulatory review period.

4 “(2) NONPROFIT LABORATORY USE.—A use of
5 subject matter by a nonprofit research laboratory or
6 other nonprofit entity, such as a university or hos-
7 pital, for which the public is the intended bene-
8 ficiary, shall be deemed to be a commercial use for
9 purposes of subsection (a)(1), except that a defense
10 under this section may be asserted pursuant to this
11 paragraph only for continued and noncommercial
12 use by and in the laboratory or other nonprofit enti-
13 ty.

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

22 “(e) LIMITATIONS AND EXCEPTIONS.—

23 “(1) PERSONAL DEFENSE.—

24 “(A) IN GENERAL.—A defense under this
25 section may be asserted only by the person who

1 performed or directed the performance of the
2 commercial use described in subsection (a), or
3 by an entity that controls, is controlled by, or
4 is under common control with such person.

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

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

23 “(2) DERIVATION.—A person may not assert a
24 defense under this section if the subject matter on

1 which the defense is based was derived from the pat-
2 entee or persons in privity with the patentee.

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

14 “(4) ABANDONMENT OF USE.—A person who
15 has abandoned commercial use (that qualifies under
16 this section) of subject matter may not rely on ac-
17 tivities performed before the date of such abandon-
18 ment in establishing a defense under this section
19 with respect to actions taken on or after the date of
20 such abandonment.

21 “(5) UNIVERSITY EXCEPTION.—

22 “(A) IN GENERAL.—A person commer-
23 cially using subject matter to which subsection
24 (a) applies may not assert a defense under this
25 section if the claimed invention with respect to

1 which the defense is asserted was, at the time
2 the invention was made, owned or subject to an
3 obligation of assignment to either an institution
4 of higher education (as defined in section
5 101(a) of the Higher Education Act of 1965
6 (20 U.S.C. 1001(a)), or a technology transfer
7 organization whose primary purpose is to facili-
8 tate the commercialization of technologies devel-
9 oped by one or more such institutions of higher
10 education.

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

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

23 “(g) INVALIDITY.—A patent shall not be deemed to
24 be invalid under section 102 or 103 solely because a de-
25 fense is raised or established under this section.”.

1 (b) CONFORMING AMENDMENT.—The item relating
2 to section 273 in the table of sections for chapter 28 of
3 title 35, United States Code, is amended to read as fol-
4 lows:

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

5 (c) EFFECTIVE DATE.—The amendments made by
6 this section shall apply to any patent issued on or after
7 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:

1 (3) TRANSITION.—
2 (A) IN GENERAL.—Chapter 31 of title 35,
3 United States Code, is amended—
4 (i) in section 312—
5 (I) in subsection (a)—
6 (aa) in the first sentence, by
7 striking “a substantial new ques-
8 tion of patentability affecting any
9 claim of the patent concerned is
10 raised by the request,” and in-
11 serting “the information pre-
12 sented in the request shows that
13 there is a reasonable likelihood
14 that the requester would prevail
15 with respect to at least 1 of the
16 claims challenged in the re-
17 quest,”; and

1 (bb) in the second sentence,
2 by striking “The existence of a
3 substantial new question of pat-
4 entability” and inserting “A
5 showing that there is a reason-
6 able likelihood that the requester
7 would prevail with respect to at
8 least 1 of the claims challenged
9 in the request”; and

10 (II) in subsection (c), in the sec-
11 ond sentence, by striking “no substan-
12 tial new question of patentability has
13 been raised,” and inserting “the show-
14 ing required by subsection (a) has not
15 been made,”; and

16 (ii) in section 313, by striking “a sub-
17 stantial new question of patentability af-
18 fecting a claim of the patent is raised” and
19 inserting “it has been shown that there is
20 a reasonable likelihood that the requester
21 would prevail with respect to at least 1 of
22 the claims challenged in the request”.

23 (B) APPLICATION.—The amendments
24 made by this paragraph—

1 (i) shall take effect on the date of the
2 enactment of this Act; and

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

8 (C) CONTINUED APPLICABILITY OF PRIOR
9 PROVISIONS.—The provisions of chapter 31 of
10 title 35, United States Code, as amended by
11 this paragraph, shall continue to apply to re-
12 quests for inter partes reexamination that are
13 filed before the effective date set forth in para-
14 graph (2)(A) as if subsection (a) had not been
15 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:

1 “(12) providing the petitioner with at least 1
2 opportunity to file written comments within a time
3 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:

1 (d) CONFORMING AMENDMENTS.—

2 (1) ATOMIC ENERGY ACT OF 1954.—Section
3 152 of the Atomic Energy Act of 1954 (42 U.S.C.
4 2182) is amended in the third undesignated para-
5 graph—

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

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

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

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

18 (B) in subsection (e), by inserting “and
19 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:

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

4 “(1) the applicant’s employer, from which the
5 applicant obtains the majority of the applicant’s in-
6 come, is an institution of higher education as de-
7 fined in section 101(a) of the Higher Education Act
8 of 1965 (20 U.S.C. 1001(a)); or

9 “(2) the applicant has assigned, granted, con-
10 veyed, or is under an obligation by contract or law,
11 to assign, grant, or convey, a license or other owner-
12 ship interest in the particular applications to such
13 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:

1 (3) PRIOR REGULATIONS NOT AFFECTED.—The
2 termination of authority under this subsection shall
3 not affect any regulations issued under this section
4 before the effective date of such termination or any
5 rulemaking proceeding for the issuance of regula-
6 tions under this section that is pending on such
7 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:

1 (i) APPROPRIATION ACCOUNT TRANSITION FEES.—

2 (1) SURCHARGE.—

3 (A) IN GENERAL.—There shall be a sur-
4 charge of 15 percent, rounded by standard
5 arithmetic rules, on all fees charged or author-
6 ized by subsections (a), (b), and (d)(1) of sec-
7 tion 41, and section 132(b), of title 35, United
8 States Code. Any surcharge imposed under this
9 subsection is, and shall be construed to be, sep-
10 arate from and in addition to any other sur-
11 charge imposed under this Act or any other
12 provision of law.

13 (B) DEPOSIT OF AMOUNTS.—Amounts col-
14 lected pursuant to the surcharge imposed under
15 subparagraph (A) shall be credited to the
16 United States Patent and Trademark Appro-
17 priation Account, shall remain available until
18 expended, and may be used only for the pur-

1 poses specified in section 42(c)(3)(A) of title
2 35, United States Code.

3 (2) EFFECTIVE DATE AND TERMINATION OF
4 SURCHARGE.—The surcharge provided for in para-
5 graph (1)—

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

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

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

15 (h) PRIORITIZED EXAMINATION FEE.—

16 (1) IN GENERAL.—

17 (A) FEE.—

18 (i) PRIORITIZED EXAMINATION
19 FEE.—A fee of \$4,800 shall be established
20 for filing a request, pursuant to section
21 2(b)(2)(G) of title 35, United States Code,
22 for prioritized examination of a nonprovi-

1 sional application for an original utility or
2 plant patent.

3 (ii) ADDITIONAL FEES.—In addition
4 to the prioritized examination fee under
5 clause (i), the fees due on an application
6 for which prioritized examination is being
7 sought are the filing, search, and examina-
8 tion fees (including any applicable excess
9 claims and application size fees), proc-
10 essing fee, and publication fee for that ap-
11 plication.

12 (B) REGULATIONS; LIMITATIONS.—

13 (i) REGULATIONS.—The Director may
14 by regulation prescribe conditions for ac-
15 ceptance of a request under subparagraph
16 (A) and a limit on the number of filings
17 for prioritized examination that may be ac-
18 cepted.

19 (ii) LIMITATION ON CLAIMS.— Until
20 regulations are prescribed under clause (i),
21 no application for which prioritized exam-
22 ination is requested may contain or be
23 amended to contain more than 4 inde-
24 pendent claims or more than 30 total
25 claims.

1 (iii) LIMITATION ON TOTAL NUMBER
2 OF REQUESTS.—The Director may not ac-
3 cept in any fiscal year more than 10,000
4 requests for prioritization until regulations
5 are prescribed under this subparagraph
6 setting another limit.

7 (2) REDUCTION IN FEES FOR SMALL ENTI-
8 TIES.—The Director shall reduce fees for providing
9 prioritized examination of nonprovisional applica-
10 tions for original utility and plant patents by 50 per-
11 cent for small entities that qualify for reduced fees
12 under section 41(h)(1) of title 35, United States
13 Code.

14 (3) DEPOSIT OF FEES.—All fees paid under
15 this subsection shall be credited to the United States
16 Patent and Trademark Office Appropriation Ac-
17 count, shall remain available until expended, and
18 may be used only for the purposes specified in sec-
19 tion 42(e)(3)(A) of title 35, United States Code.

20 (4) EFFECTIVE DATE AND TERMINATION.—

21 (A) EFFECTIVE DATE.—This subsection
22 shall take effect on the date that is 10 days
23 after the date of the enactment of this Act.

24 (B) TERMINATION.—The fee imposed
25 under paragraph (1)(A)(i), and the reduced fee

1 under paragraph (2), shall terminate on the ef-
2 fective date of the setting or adjustment of the
3 fee under paragraph (1)(A)(i) pursuant to the
4 exercise of the authority under section 10 for
5 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 pro-
vided in this section,”.

Page 105, strike lines 1 through 11.

Page 105, add the following after line 25 and redesi-
gnate the succeeding subsection accordingly:

6 “(e) FRAUD.—If the Director becomes aware, during
7 the course of a supplemental examination or reexamina-
8 tion proceeding ordered under this section, that a material
9 fraud on the Office may have been committed in connec-
10 tion with the patent that is the subject of the supplemental
11 examination, then in addition to any other actions the Di-
12 rector is authorized to take, including the cancellation of
13 any claims found to be invalid under section 307 as a re-
14 sult of a reexamination ordered under this section, the Di-
15 rector shall also refer the matter to the Attorney General
16 for such further action as the Attorney General may deem
17 appropriate. Any such referral shall be treated as con-
18 fidential, shall not be included in the file of the patent,

1 and shall not be disclosed to the public unless the United
2 States charges a person with a criminal offense in connec-
3 tion with such referral.

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

4 “(c) The marking of a product, in a manner described
5 in subsection (a), with matter relating to a patent that
6 covered that product but has expired is not a violation of
7 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
2 may waive the limitations set forth in this section with
3 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:

1 (k) ADDITIONAL TECHNICAL AMENDMENTS.—Sec-
2 tions 155 and 155A of title 35, United States Code, and
3 the items relating to those sections in the table of sections
4 for chapter 14 of such title, are repealed.

Page 130, strike line 3 and all that follows through
page 134, line 17, and insert the following:

5 **SEC. 22. PATENT AND TRADEMARK OFFICE FUNDING.**

6 (a) IN GENERAL.—Section 42(c) of title 35, United
7 States Code, is amended—

8 (1) by striking “(c)” and inserting “(c)(1)”;

9 (2) in the first sentence, by striking “shall be
10 available” and inserting “shall, subject to paragraph
11 (3), be available”;

12 (3) by striking the second sentence; and

13 (4) by adding at the end the following:

14 “(2) There is established in the Treasury a Patent
15 and Trademark Fee Reserve Fund. If fee collections by
16 the Patent and Trademark Office for a fiscal year exceed
17 the amount appropriated to the Office for that fiscal year,
18 fees collected in excess of the appropriated amount shall
19 be deposited in the Patent and Trademark Fee Reserve
20 Fund. To the extent and in the amounts provided in ap-
21 propriations Acts, amounts in the Fund shall be made
22 available until expended only for obligation and expendi-
23 ture by the Office in accordance with paragraph (3).

1 “(3)(A) Any fees that are collected under sections 41,
2 42, and 376, and any surcharges on such fees, may only
3 be used for expenses of the Office relating to the proc-
4 essing of patent applications and for other activities, serv-
5 ices, and materials relating to patents and to cover a share
6 of the administrative costs of the Office relating to pat-
7 ents.

8 “(B) Any fees that are collected under section 31 of
9 the Trademark Act of 1946, and any surcharges on such
10 fees, may only be used for expenses of the Office relating
11 to the processing of trademark registrations and for other
12 activities, services, and materials relating to trademarks
13 and to cover a share of the administrative costs of the
14 Office relating to trademarks.”

15 (b) EFFECTIVE DATE.—The amendments made by
16 this section shall take effect on October 1, 2011.

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:

1 **SEC. 27. STUDY ON GENETIC TESTING.**

2 (a) IN GENERAL.—The Director shall conduct a
3 study on effective ways to provide independent, confirming
4 genetic diagnostic test activity where gene patents and ex-
5 clusive licensing for primary genetic diagnostic tests exist.

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

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

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

18 (3) The impact that current exclusive licensing
19 and patents on genetic testing activity has on the

1 practice of medicine, including but not limited to:
2 the interpretation of testing results and performance
3 of testing procedures.

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

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

15 (d) REPORT.—Not later than 9 months after the date
16 of enactment of this Act, the Director shall report to the
17 Committee on the Judiciary of the Senate and the Com-
18 mittee on the Judiciary of the House of Representatives
19 on the findings of the study and provide recommendations
20 for establishing the availability of such independent con-
21 firming genetic diagnostic test activity.

22 **SEC. 28. PATENT OMBUDSMAN PROGRAM FOR SMALL BUSI-**
23 **NESS CONCERNS.**

24 Using available resources, the Director shall establish
25 and maintain in the Office a Patent Ombudsman Pro-

1 gram. The duties of the Program's staff shall include pro-
2 viding support and services relating to patent filings to
3 small business concerns and independent inventors.

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

4 **SEC. 30. LIMITATION ON ISSUANCE OF PATENTS.**

5 (a) LIMITATION.—Notwithstanding any other provi-
6 sion of law, no patent may issue on a claim directed to
7 or encompassing a human organism.

8 (b) EFFECTIVE DATE.—

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

13 (2) PRIOR APPLICATIONS.—Subsection (a) shall
14 not affect the validity of any patent issued on an ap-
15 plication to which paragraph (1) does not apply.

16 **SEC. 31. STUDY OF PATENT LITIGATION.**

17 (a) GAO STUDY.—The Comptroller General of the
18 United States shall conduct a study of the consequences
19 of litigation by non-practicing entities, or by patent asser-
20 tion entities, related to patent claims made under title 35,
21 United States Code, and regulations authorized by that
22 title.

1 (b) CONTENTS OF STUDY.—The study conducted
2 under this section shall include the following:

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

6 (2) The volume of cases comprising such litiga-
7 tion that are found to be without merit after judicial
8 review.

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

11 (4) The estimated costs, including the esti-
12 mated cost of defense, associated with such litigation
13 for patent holders, patent licensors, patent licensees,
14 and inventors, and for users of alternate or com-
15 peting innovations.

16 (5) The economic impact of such litigation on
17 the economy of the United States, including the im-
18 pact on inventors, job creation, employers, employ-
19 ees, and consumers.

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

23 (c) REPORT TO CONGRESS.—The Comptroller Gen-
24 eral shall, not later than the date that is 1 year after the
25 date of the enactment of this Act, submit to the Com-

1 mittee on the Judiciary of the House of Representatives
2 and the Committee on the Judiciary of the Senate a report
3 on the results of the study required under this section,
4 including recommendations for any changes to laws and
5 regulations that will minimize any negative impact of pat-
6 ent litigation that was the subject of such study.

