

H.R. 1540, Rollcall Vote No. 341, had I been present I would have voted "yes."

On Agreeing to the Resolution, H. Res. 276, Providing for further consideration of H.R. 1540, Rollcall Vote No. 342, had I been present I would have voted "yes."

On the amendment of Ms. WOOLSEY of California, Amendment No. 2 to H.R. 1540, Rollcall Vote No. 343, had I been present I would have voted "no."

On the amendment of Mr. HUNTER of California, Amendment No. 12 to H.R. 1540, Rollcall Vote No. 344, had I been present I would have voted "no."

On the amendment of Mr. SARBANES of Maryland, Amendment No. 24 to H.R. 1540, Rollcall Vote No. 345, had I been present I would have voted "no."

On the amendment of Mr. MURPHY of Connecticut, Amendment No. 25 to H.R. 1540, Rollcall Vote No. 346, had I been present I would have voted "no."

On the amendment of Mr. COLE of Oklahoma, Amendment No. 27 to H.R. 1540, Rollcall Vote No. 347, had I been present I would have voted "yes."

On the amendment of Mr. GARAMENDI of California, Amendment No. 28 to H.R. 1540, Rollcall Vote No. 348, had I been present I would have voted "no."

On the amendment of Ms. MALONEY of New York, Amendment No. 26 to H.R. 1540, Rollcall Vote No. 349, had I been present I would have voted "no."

On the amendment of Mr. HIMES of Connecticut, Amendment No. 30 to H.R. 1540, Rollcall Vote No. 350, had I been present I would have voted "no."

On the amendment of Ms. JACKSON LEE of Texas, Amendment No. 31 to H.R. 1540, Rollcall Vote No. 351, had I been present I would have voted "no."

On the amendment of Mr. ANDREWS of New Jersey, Amendment No. 32 to H.R. 1540, Rollcall Vote No. 352, had I been present I would have voted "no."

On the amendment of Mr. RICHMOND of Louisiana, Amendment No. 37 to H.R. 1540, Rollcall Vote No. 353, had I been present I would have voted "no."

On the amendment of Mr. MICA of Florida, Amendment No. 38 to H.R. 1540, Rollcall Vote No. 354, had I been present I would have voted "yes."

On the amendment of Mr. FLAKE of Arizona, Amendment No. 40 to H.R. 1540, Rollcall Vote No. 355, had I been present I would have voted "yes."

On the amendment of Mr. SMITH of Washington, Amendment No. 42 to H.R. 1540, Rollcall Vote No. 356, had I been present I would have voted "no."

On the amendment of Mr. BUCHANAN of Florida, Amendment No. 43 to H.R. 1540, Rollcall Vote No. 357, had I been present I would have voted "yes."

On the amendment of Ms. MALONEY of New York, Amendment No. 47 to H.R. 1540, Rollcall Vote No. 358, had I been present I would have voted "no."

On the amendment of Mr. MACK of Florida, Amendment No. 48 to H.R. 1540, Rollcall Vote No. 359, had I been present I would have voted "yes."

On the amendment of Mr. LANGEVIN of Rhode Island, Amendment No. 49 to H.R. 1540, Rollcall Vote No. 360, had I been present I would have voted "no."

On the amendment of Mr. AMASH of Michigan, Amendment No. 50 to H.R. 1540, Rollcall Vote No. 361, had I been present I would have voted "no."

On the amendment of Mr. CAMPBELL of California, Amendment No. 53 to H.R. 1540, Rollcall Vote No. 362, had I been present I would have voted "no."

On the amendment of Mr. CAMPBELL of California, Amendment No. 54 to H.R. 1540, Rollcall Vote No. 363, had I been present I would have voted "no."

On the amendment of Mr. CHAFFETZ of Utah, Amendment No. 56 to H.R. 1540, Rollcall Vote No. 364, had I been present I would have voted "no."

On the amendment of Mr. POLIS of Colorado, Amendment No. 60 to H.R. 1540, Rollcall Vote No. 365, had I been present I would have voted "no."

On the amendment of Mr. CONYERS of Michigan, Amendment No. 61 to H.R. 1540, Rollcall Vote No. 366, had I been present I would have voted "yes."

On the amendment of Mr. FLAKE of Arizona, Amendment No. 62 to H.R. 1540, Rollcall Vote No. 367, had I been present I would have voted "no."

On the amendment of Mr. ELLISON of Minnesota, Amendment No. 63 to H.R. 1540, Rollcall Vote No. 368, had I been present I would have voted "no."

On the amendment of Ms. LORETTA SANCHEZ of California, Amendment No. 64 to H.R. 1540, Rollcall Vote No. 369, had I been present I would have voted "no."

On the amendment of Ms. JACKSON LEE of Texas, Amendment No. 111 to H.R. 1540, Rollcall Vote No. 370, had I been present I would have voted "yes."

On the amendment of Mr. TURNER of Ohio, Amendment No. 148 to H.R. 1540, Rollcall Vote No. 371, had I been present I would have voted "yes."

On the amendment of Mr. CRAVAACK of Minnesota, Amendment No. 152 to H.R. 1540, Rollcall Vote No. 372, had I been present I would have voted "yes."

On the amendment of Mr. MCGOVERN of Massachusetts, Amendment No. 55 to H.R. 1540, Rollcall Vote No. 373, had I been present I would have voted "no."

On Motion to Recommit with Instructions H.R. 1540, Rollcall Vote No. 374, had I been present I would have voted "no."

On Passage of H.R. 1540, to authorize appropriations for fiscal year 2012 for military activities of the Department of Defense and for military construction, to prescribe military personnel strengths for fiscal year 2012, and for other purposes, Rollcall Vote No. 375, had I been present I would have voted "yes."

On Motion to Concur in the Senate Amendment to the House Amendment, S. 990, the Small Business Additional Temporary Extension Act of 2011, Rollcall Vote No. 376, had I been present I would have voted "yes."

consideration the bill (H.R. 1249) to amend title 35, United States Code, to provide for patent reform:

Mr. SMITH of Texas. Madam Chair, I submit: (1) Manager's Statement on Supplemental Examination; (2) Manager's Statement on Genetic Test Study proposed in the Managers; (3) Statement on the codification of the Weldon amendment; (4) Statement on the business method patent transitional program; (5) Statement on the PTO fee compromise provision in the Manager's amendment; (6) November 2003 letter on the Weldon amendment from PTO Director James Rogan; (7) Information on the Weldon amendment from the Family Research Council.

CHAIRMAN'S FLOOR REMARKS/MANAGER'S STATEMENT: SUPPLEMENTAL EXAMINATION IN H.R. 1249

Mr. Speaker, this bill also contains a very important new administrative proceeding available to patent owners, to help improve the quality of issued patents. This new "Supplemental Examination" procedure encourages the voluntary and proactive disclosure of information that may be relevant to patent prosecution for the Office to consider, reconsider, or correct. The voluntary disclosure by patentees serves to strengthen valid patents, while narrowing or eliminating patents or claims that should not have been issued. Both of these outcomes promote investment in innovation by removing uncertainty about the scope, validity or enforceability of patents, and thus the use of this new proceeding by patent owners is to be encouraged.

Subparagraph (C) relating to Supplemental Examination is intended to address the circumstance where, during the course of a supplemental examination or reexamination proceeding ordered under this section, a court or administrative agency advises the PTO that it has made a determination that a fraud on the Office may have been committed in connection with the patent that is the subject of the supplemental examination. In such a circumstance, subparagraph (C) provides that, 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 the reexamination ordered under this section, the Director shall also refer the matter to the Attorney General. As such, this provision is not intended to impose any obligation on the PTO beyond those it already undertakes, or require it to investigate or prosecute any such potential fraud. Subparagraph (C) is neither an investigative nor an adjudicative provision, and, as such, is not intended to expand the authority or obligation of the PTO to investigate or adjudicate allegations of fraud lodged by private parties.

Further, any referral under this subsection is not meant to relieve the Director from his obligation to conclude the supplemental examination or reexamination proceeding ordered under this section. It is important for the process to proceed through conclusion of reexamination, so that any claims that are invalid can be properly cancelled.

The decision to make referrals under subsection (c) is not meant to be delegated to examiners or other agents of the PTO, but rather is a determination that should only be made by the Director himself or herself.

Supplemental Examination has the potential to play a powerful role in improving patent quality and boosting investment in innovation, economic growth, and job creation. The Director should implement this new authority in a way that maximizes this potential.

AMERICA INVENTS ACT

SPEECH OF

HON. LAMAR SMITH

OF TEXAS

IN THE HOUSE OF REPRESENTATIVES

Wednesday, June 22, 2011

The House in Committee of the Whole House on the State of the Union had under

GENETIC TEST STUDY IN MANAGER'S
AMENDMENT (DWS)

Mr. Speaker, Section 27 of H.R. 1249 requires the Director of the U.S. Patent and Trademark Office to conduct a study on the availability of confirmatory genetic diagnostic testing services in the domestic market, and whether changes to existing patent law are necessary to promote such availability more effectively. Consistent with current law, the genetic inventions that form the basis for such diagnostic tests are eligible for patenting, and may be exclusively licensed by such patent holders for genetic diagnostic purposes.

This study is intended to provide unbiased, reliable, and empirical information about the existing availability of independent confirmatory genetic diagnostic testing services, as well as patient demand for such testing services, in situations where genetic diagnostic tests are indeed patented and exclusively licensed. Nothing in this section shall be construed as undermining existing patent law in this regard.

This study is intended to include, but is not limited to, several specific aspects of this issue. Paragraph (1) of subsection (b) requires an assessment of whether the existing level of availability of confirmatory genetic diagnostic testing has an impact on the ability of medical professionals to provide the appropriate standard of medical care to recipients of genetic diagnostic testing, and includes an assessment of the role that patents play in innovation, quality of services, and investment in the genetic diagnostic marketplace. The assessment required by this paragraph also should include empirical information about the extent to which patents have actually been enforced or asserted against the unauthorized practice of confirmatory genetic diagnostic tests, and a comparison of the availability of and demand for confirmatory testing in situations where genetic tests are not patented or are non-exclusively licensed. Paragraph (2) requires the Director to assess the effects of independent, unauthorized confirmatory genetic testing on patent holders or exclusively licensed test providers. The Committee urges the Director to include in this assessment the possible effects of allowing confirmatory testing on authorized providers of non-exclusively licensed genetic diagnostic tests as well, given that such authorized providers may already provide confirmatory testing services. Paragraph (3) requires an evaluation of the impact of patents and exclusive licensing of genetic diagnostic tests on the practice of medicine, including, but not limited to, the ability of medical professionals to interpret test results, and the ability of licensed or unlicensed test providers to provide confirmatory genetic diagnostic tests. The Director's assessment should also include information on the frequency at which confirmatory genetic diagnostic testing currently is performed by medical professionals in instances where an absence of patent protection or non-exclusive licensing permits multiple independent test providers. Paragraph (4) requires an assessment of the role that cost and insurance coverage have on access to and provision of confirmatory genetic diagnostic tests today, whether patented or not or exclusively licensed or not, and should include an assessment of whether private and public payors cover such costs and are likely to cover the costs of any expansion of confirmatory testing."

Additional Legislative History for the Second Opinion Confirmation Test Study in Managers (H.R. 1249): Additional Information for the Record:

"Section 27 requires USPTO to conduct a study on the impact that a lack of inde-

pendent second opinion testing has on providing medical care to patients and recipients of genetic diagnostic testing, the effect that providing such tests would have on patent holders of exclusive genetic tests, the impact the current exclusive licensing and patents on genetic testing activity has on the practice of medicine, and the role that cost and insurance coverage have on access to genetic diagnostic tests. Nothing in Section 27 shall be construed to reflect any expression by the Congress with respect to the patentability or non-patentability of genetic material or with respect to the validity or invalidity of patents on genetic material."

THE WELDON AMENDMENT

"None of the funds appropriated or otherwise made available by this act may be used to issue patents on claims directed to or encompassing a human organism."

Legislative History:

The legislation prohibits the use of appropriated funds by the Patent and Trademark Office to issue certain types of claims presented in patent applications. The types of patent claims subject to the prohibition are limited precisely to those that the Patent and Trademark Office, pursuant to its policies, has indicated may not be granted (see M.P.E.P 1st rev. 2105). Specifically, this section operates to prohibit the use of appropriated funds to issue a patent containing claim that encompasses a human individual.

The Committee recognizes that the economic viability of the biotechnology industry requires that patents be available for the full spectrum of innovation that may be subject to commercialization. The legislation, accordingly does not limit patent eligibility for any type of biotechnology invention that may be commercialized in the United States. The Committee also recognizes that continued innovation in the biomedical and biotechnological fields will lead to new kinds of inventions, and it expects that the overwhelming majority of such inventions will not raise any of the concerns that the present legislation addresses. In particular, nothing in this section should be construed to limit the ability of the PTO to issue a patent containing claims directed to or encompassing:

1. any chemical compound or composition, whether obtained from animals or human beings or produced synthetically, and whether identical to or distinct from a chemical structure as found in an animal or human being, including but not limited to nucleic acids, polypeptides, proteins, antibodies and hormones;
2. cells, tissue, organs or other bodily components produced through human intervention, whether obtained from animals, human beings, or other sources; including but not limited to stem cells, stem cell derived tissues, stem cell lines, and viable synthetic organs;
3. methods for creating, modifying, or treating human organisms, including but not limited to methods for creating embryos through in vitro fertilization, methods of somatic cell nuclear transfer, medical or genetic therapies, methods for enhancing fertility, and methods for implanting embryos;
4. a nonhuman organism incorporating one or more genes taken from a human organism, including but not limited to a transgenic plant or animal, or animal models used for scientific research.

As the legislation addresses only the authority of the PTO to expend funds appropriated by this Act, it concerns patents that may issue on applications filed on or after the date of the legislation. The legislation does not create a claim or give rise to any cause of action to limit the rights associated

with, or the enforceability of any patent duly granted by the PTO.

SECTION 18 (H.R. 1249)—BUSINESS METHOD
PATENT TRANSITIONAL PROGRAM

The proceeding would create a cheap and speedy alternative to litigation—allowing parties to resolve these disputes rather than spend millions of dollars that litigation now costs. In the process, the proceeding would also prevent nuisance or extortion litigation settlements.

Business methods were generally not patentable in the United States before the late 1990s, and generally are not patentable elsewhere in the world, but the Federal Circuit (in what was an activist decision) created a new class of patents in its 1998 State Street decision.

In its 2010 decision in *Bilski v. Kappos*, the U.S. Supreme Court clamped down on the patenting of business methods and other patents of poor quality.

It is likely that most if not all the business method patents that were issued after State Street are now invalid under *Bilski*. There is no sense in allowing expensive litigation over patents that are no longer valid.

This provision is strongly supported by community banks, credit unions and other institutions that are an important source of lending to homeowners and small businesses. Money spent litigating over invalid business-method patents, or paying nuisance settlements, cannot be loaned to Americans to purchase new homes and start new businesses.

Resolving the validity of these patents in civil litigation typically costs about \$5-to-\$10 million per patent. Resolving the validity of these patents through the bill's administrative proceeding costs much less.

Moreover, the proceeding allows business-method patents to be reviewed by the experts at the Patent Office under the correct (*Bilski*) standard.

To use this proceeding, a challenger must make an up-front showing to the PTO of evidence that the business-method patent is more likely than not invalid. This is a high standard. Only the worst patents, which probably never should have been issued, will be eligible for review in this proceeding.

Additionally any argument about this provision and Constitutionality is simply a red herring. Congress has the authority to create administrative proceedings to review the validity of existing patents. We have done it before and we will be doing it in the future.

This issue has been litigated and rejected by the courts, when Congress created *ex parte reexam* in 1980. *Ex parte reexam* was applied to all existing patents when that system was created. In *Patlex Corp. v. Mossinghoff*, the Federal Circuit rejected the argument that applying a new system of administrative review to existing patents is a taking. The same logic applies to this provision.

Never in the history of U.S. patent law has it been held, after a patent claim was determined to be invalid because it covered unprotectable subject matter, that the owner of the patent was nevertheless entitled to compensation on the basis of that invalid claim.

This section only creates a new mechanism for reviewing the validity of business-method patents. It does not alter the substantive law governing the validity of those patents. Under settled precedent, the transitional review program is absolutely constitutional.

It is wrong and offensive for this provision to be referred to as a bail-out. The program does not give one cent to any private party and the costs of the proceeding are required to be fully recouped through the fee charged

for initiating the proceeding. It is a necessary program to allow the PTO to fix mistakes that occurred in light of an activist judicial decision in the 1998 State Street decision that created this new patentable subject matter without Congress' approval.

This bill will provide the patent office with a fast, precise vehicle to review low quality business method patents, which the Supreme Court has acknowledged are often abstract and overly broad.

And it bears repeating that defendants cannot even start this program unless they can persuade a panel of judges at the outset of the proceeding that it is more likely than not that the patent is invalid. This is a high threshold, which requires the challenger to present his best evidence and arguments at the outset. Very few patents that undergo this review are likely to be valid patents.

Specifically, the bill's provision applies to patents that describe a series of steps used to conduct every day business applications in the financial products and retail service space. These are patents that can be and have been asserted against all types of businesses—from community banks and credit unions to retailers like Walmart, Bed Bath & Beyond, Best Buy, J.C. Penney, Staples and Office Max to other companies like Dr. Pepper Snapple Group, UPS, Hilton, AT&T, Facebook, Frito-Lay, Google, Marriott, Walt Disney, Delta Airlines and YouTube.

This provision is not tied to one industry or sector of the economy—it affects everyone. For example, this program would allow the Patent Office to decide whether to review patents for business methods related to:

Printing ads at the bottom of billing statements

Buying something online and picking it up in the store

Re-ordering checks online

Converting a IRA to a Roth IRA

Getting a text message when you use your credit card

Those who argue that this provision is a Wall Street bailout are just plain wrong. This is about questionable patents and the frivolous litigation that results from them. This provision is important legal reform, supported by the U.S. Chamber of Commerce and is important for American job creators.

PTO FEE DIVERSION COMPROMISE (H.R. 1249 MANAGERS)

By giving USPTO access to all its funds, the Manager's Amendment supports the USPTO's efforts to improve patent quality and reduce the backlog of patent applications. To carry out the new mandates of the legislation and reduce delays in the patent application process, the USPTO must be able to use all the fees it collects.

The language in the Manager's Amendment reflects the intent of the Judiciary Committee, the Appropriations Committee, and House leadership to end fee diversion. USPTO is 100% funded by fees paid by inventors and trademark filers who are entitled to receive the services they are paying for. The language makes clear the intention not only to appropriate to the USPTO at least the level requested for the fiscal year but also to appropriate to the USPTO any fees collected in excess of such appropriation.

Providing USPTO access to all fees collected means providing access at all points during that year, including in case of a continuing resolution. Access also means that reprogramming requests will be acted on within a reasonable time period and on a reasonable basis. It means that future appropriations will continue to use language that guarantees USPTO access to all of its fee collections.

UNITED STATES PATENT AND TRADEMARK OFFICE, UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND DIRECTOR OF THE U.S. PATENT AND TRADEMARK OFFICE,

Alexandria, VA.

Hon. TED STEVENS,
Chairman, Committee on Appropriations, U.S. Senate, Washington, DC.

DEAR MR. CHAIRMAN: Thank you for the opportunity to present the Administration's position on the Weldon amendment adopted by the House during consideration of H.R. 2799, the Commerce-Justice-State Appropriations bill FY 2004, and the effect it would have on the United States Patent and Trademark Office (USPTO) policy on patenting living subject matter. For the reasons outlined below, we view the Weldon amendment as fully consistent with USPTO's policy on the non-patentability of human life-forms.

The Weldon Amendment would prohibit the U.S. Patent and Trademark Office from issuing any patent "on claims directed to or encompassing a human organism." The USPTO understands the Weldon Amendment to provide unequivocal congressional backing for the long-standing USPTO policy of refusing to grant any patent containing a claim that encompasses any member of the species *Homo sapiens* at any stage of development. It has long been USPTO practice to reject any claim in a patent application that encompasses a human life-form at any stage of development, including a human embryo or human fetus; hence claims directed to living "organisms" are to be rejected unless they include the adjective "nonhuman."

The USPTO's policy of rejecting patent application claims that encompass human life-forms, which the Weldon Amendment elevates to an unequivocal congressional prohibition, applies regardless of the manner and mechanism used to bring a human organism into existence (e.g., somatic cell nuclear transfer, in vitro fertilization, parthenogenesis). If a patent examiner determines that a claim is directed to a human life-form at any stage of development, the claim is rejected as non-statutory subject matter and will not be issued in a patent as such.

As indicated in Representative Weldon's remarks in the Congressional Record of November 5, 2003, the referenced language precludes the patenting of human organisms, including human embryos. He further indicated that the amendment has "exactly the same scope as the current USPTO policy," which assures that any claim that can be broadly construed as a human being, including a human embryo or fetus, is not patentable subject matter. Therefore, our understanding of the plain language of the Weldon Amendment is fully consistent with the detailed statements that the author of the amendment, Representative Weldon, has made in the Congressional Record regarding the meaning and intent of his amendment.

Given that the scope of Representative Weldon's amendment does not alter the USPTO policy on the non-patentability of human life-forms at any stage of development and is fully consistent with our policy, we support its enactment.

With best personal regards, I remain

Sincerely,

JAMES E. ROGAN,
Under Secretary and Director.

FRC ACTION,
FAMILY RESEARCH COUNCIL.

CODIFY THE WELDON BAN ON PATENTING HUMANS

CURRENT WELDON PATENT BAN ON HUMANS

The Weldon Amendment is contained in the annual Commerce, Justice and Science

Appropriations bills (CJS) and prevents the patenting of humans. Congress has passed it each year since 2004, and it was included most recently as part of the FY2010 Omnibus (Section 518, Title V, Division B, of the FY2010 Consolidated Appropriations Act, 2010 (H.R. 3288, P.L. 111-117)) and extended by the FY2011 Omnibus spending bill (Department of Defense and Full-Year Continuing Appropriations Act, 2011 (H.R. 1473, P.L. 112-10)).

Weldon Amendment, Section 518: "None of the friends appropriated or otherwise made available under this Act may be used to issue patents on claims directed to or encompassing a human organism."

CODIFY THE WELDON AMENDMENT—ADD IT TO PATENT REFORM LEGISLATION

Congress has each year since 2004 passed the Weldon Amendment to prevent any profiting from patents on humans. The Weldon Amendment restricts funds under the Commerce, Justice, Science Appropriations bill from being used by the U.S. Patent and Trademark Office (USPTO) to issue patents directed to "human organisms."

The America Invents Act (H.R. 1249) may authorize the USPTO to pay for the issuance of patents with "user fees" instead of with Congressionally appropriated funds. If this funding mechanism becomes law, the Weldon Amendment restriction would not apply since it only covers funds appropriated under the CJS bill. The USPTO could, thereby, issue patents directed to human beings with non-appropriated funds.

Patenting human beings at any stage of development would overturn the long-standing USPTO policy against issuing such patents. As the Quigg Memo stated in 1987 (see below) a grant of a property right in a human being is unconstitutional, and patents on humans are grounds for rejection.

The Weldon restriction can be codified by adding a provision to the America Invents Act to ensure that human beings are not patentable subject matter.

Codifying a ban on patenting of humans would not violate international obligations under the TRIPs agreement with the WTO. The European Union prevents patents on human embryos on the ground that doing so would violate the public order and morality, an exception the TRIPs agreement specifically allows under Article 27, Section 5.

WHAT THE WELDON PATENT AMENDMENT DOES AND DOES NOT AFFECT

The Weldon Amendment does prevent the USPTO from patenting humans at any stage of development, including embryos or fetuses, by preventing patents on claims directed to "human organisms."

The Weldon Amendment's use of the term "human organism" does include human embryos, human fetuses, human-animal chimeras, "she-male" human embryos, or human embryos created with genetic material from more than one embryo.

The Weldon Amendment's use of "human organism" does not include the process of creating human embryos, such as human cloning, nor does it include non-human organisms, e.g., animals.

Then Undersecretary James Rogan wrote to Senate Appropriators on November 20, 2003 stating that the Weldon Amendment gave congressional backing to long-standing USPTO policy against patenting humans stating:

"The Weldon Amendment would prohibit the U.S. Patent and Trademark Office from issuing any patent "on claims directed to or encompassing a human organism." The USPTO understands the Weldon Amendment to provide unequivocal congressional backing for the long-standing USPTO policy of refusing to grant any patent containing a claim that encompasses any member of the

species *Homo sapiens* at any stage of development. It has long been USPTO practice to reject any claim in a patent application that encompasses a human life-form at any stage of development, including a human embryo or human fetus; hence claims directed to living "organisms" are to be rejected unless they include the adjective "nonhuman."

Secretary Rogan concluded: "The USPTO's policy of rejecting patent application claims that encompass human life-forms, which the Weldon Amendment elevates to an unequivocal congressional prohibition, applies regardless of the manner and mechanism used to bring a human organism into existence (e.g., somatic cell nuclear transfer, in vitro fertilization, parthenogenesis). If a patent examiner determines that a claim is directed to a human life-form at any stage of development, the claim is rejected as non-statutory subject matter and will not be issued in a patent as such."

The Weldon Amendment does not prevent patents on human cells, genes, or other tissues obtained from human embryos or human bodies.

Rep. Dave Weldon submitted a statement to the Congressional Record on December 8, 2003 clarifying that the Weldon Amendment would not prevent patents for non-human organisms even with some human genes. Nor would it affect patents for human cells, tissues or body parts, or for methods of creating human embryos.

Rep. Weldon stated: "This amendment should not be construed to affect claims directed to or encompassing subject matter other than human organisms, including but not limited to claims directed to or encompassing the following: cells, tissues, organs, or other bodily components that are not themselves human organisms (including, but not limited to, stem cells, stem cell lines, genes, and living or synthetic organs); hormones, proteins or other substances produced by human organisms; methods for creating, modifying, or treating human organisms, including but not limited to methods for creating human embryos through in vitro fertilization, somatic cell nuclear transfer, or parthenogenesis; drugs or devices (including prosthetic devices) which may be used in or on human organisms."

The Weldon amendment does not ban human stem cell patents, including patents on human embryonic stem cells. "Stem cells" are not "organisms."

On December 2, 1998, several scientists supportive of federal funding of human embryonic stem cell research testified before the Senate Subcommittee on Labor, Health and Human Services, and Education Committee on Appropriations that "stem cells" are not "human organisms." When asked, Dr. James Thomson who first obtained human embryonic stem cells, and has patents on those stem cell lines, responded: "They are not organisms and they are not embryos."

Despite claims in 2003 that the Weldon amendment in 2003 would ban stem cell patents, the USPTO has maintained several embryonic stem cell patents issued previously. The USPTO has also issued several new patents on human embryonic stem cells since 2003, and has issued roughly 300 new patents on pluripotent stout cells. The Weldon amendment only affects patents on human organisms. (Note, the EU recently reaffirmed its rejection of patents on embryonic stem cells, yet, the Weldon amendment does not follow suit).

HISTORY AND BACKGROUND

Longstanding United States Patent and Trademark Office (USPTO) policy states that human beings at any stage of development are not patentable subject matter under 35 U.S.C. Section 101. In 1980, the U.S.

Supreme Court in *Diamond v Chakrabarty* expanded the scope of patentable subject matter claiming Congress intended statutory subject matter to "include anything under the sun that is made by man." The USPTO eventually issued patents directed to non-human organisms, including animals. However, the USPTO rejected patents on humans (see below).

However, as early as 2003 U.S. researchers announced that they created human male-female embryos and reportedly wanted to patent this research (<http://www.thenewatlantis.com/publications/my-mother-the-embryo>). The researchers transplanted cells from male embryos into female embryos and allowed them to grow for six days.

Because of the possibility of court challenges to USPTO policy, Rep. Dave Weldon offered an amendment on July 22, 2003 to the CJS Appropriations bill to prevent funding for patents directed to "human organisms."

The Weldon amendment was adopted by voice vote, and was included as Section 634, Title VI of Division B, in the Consolidated Appropriations Act, 2004 (P.L. 108-199). The accompanying report language clarified its scope: "The conferees have included a provision prohibiting funds to process patents of human organisms. The conferees concur with the intent of this provision as expressed in the colloquy between the provisions sponsor in the House and the ranking minority member of the House Committee on Appropriations as occurred on July 22, 2003, with respect to any existing patents on stem cells." (Conference Report 108-401).

The Weldon amendment has been included each year in the CJS appropriations bill since 2004 and reflected the USPTO policy against patenting humans as outlined in 3 USPTO official documents.

First, the USPTO published the "Quigg memo" in its Official Gazette on January 5, 1993, which was written in 1917 stating: "The Patent and Trademark Office now considers nonnaturally occurring non-human multicellular living organisms, including animals, to be patentable subject matter within the scope of 35 U.S.C. 101. . . . A claim directed to or including within its scope a human being will not be considered patentable subject matter under 35 U.S.C. 101." Furthermore, it "suggests" that that any claim directed to "a non-plant multicellular organism which would include a human being within its scope include the limitation 'non-human' to avoid this ground of rejection."

Second, the USPTO policy is also contained in an official media advisory issued on April 2, 1998 in response to news about a patent application directed to a human/non-human chimera. USPTO claimed that patents "inventions directed to human/non-human chimera could, under certain circumstances, not be patentable because, among other things, they would fail to meet the public policy and morality aspects of the utility requirement."

Third, the USPTO policy is contained in the Manual of Patent Examining Procedure (MPEP) section 2105 under "Patentable Subject Matter." The MPEP states that the USPTO "would now consider nonnaturally occurring, nonhuman multicellular living organisms, including animals, to be patentable subject matter within the scope of 35 U.S.C. 101. If the broadest reasonable interpretation of the claimed invention as a whole encompasses a human being, then a rejection under 35 U.S.C. 101 must be made indicating that the claimed invention is directed to non-statutory subject matter."

HONORING C. FREDERICK
ROBINSON

HON. DALE E. KILDEE

OF MICHIGAN

IN THE HOUSE OF REPRESENTATIVES

Thursday, June 23, 2011

Mr. KILDEE. Mr. Speaker, it is with a profound sadness that I rise today to pay tribute to a dear friend, Attorney C. Frederick Robinson, who passed away on Saturday, June 18th in Flint Michigan.

C. Frederick Robinson moved to Flint after receiving his Doctorate of Jurisprudence from Howard University in 1956. He was admitted to the State Bar of Michigan and established his practice in an office at the corner of Saginaw and Baker Streets. He practiced law in the City of Flint continuously since that time. From the beginning of his career, C. Frederick was an outstanding advocate for justice. He was a passionate fighter for the poor, disenfranchised and minority communities and I have been his friend for over 50 years.

As a leader in the civil rights movement, C. Frederick's list of landmark cases is extensive. He initiated the complaint that ended the Flint Board of Education practice of separate screening committees for black and white teachers. He initiated the lawsuit that ended the Flint Memorial Park Cemetery practice of not allowing blacks to be buried at the cemetery. He participated in the lawsuit that declared the local loitering ordinance unconstitutional. He led the effort to have the first black to be elected to the Flint Board of Education and the fight to have the first black female elected to the same body. He was instrumental in the election of the first black Secretary of State in Michigan. He participated in the lawsuit to allow the NAACP to erect a platform at Flint City Hall to hold a rally. He also represented Clifford Scott in a lawsuit to enact Affirmative Action in the construction business.

In 1968 C. Frederick Robinson helped shape civil rights history in the United States. He and his partner, A. Glen Epps, wrote Flint's open housing ordinance. I remember numerous open housing strategy sessions at C. Frederick's office, the 50 Grand Club, the Vets Club, and the Golden Leaf. I also recall the picket lines which brought Governor George Romney to Flint for a unity rally that drew thousands. The ordinance was placed on the ballot and C. Frederick was determined it would pass. C. Frederick was tireless in his efforts to galvanize the community when working on the fair housing referendum. When the vote was taken on February 20, 1968, Flint became the first city in the nation to pass by popular vote an open housing referendum. C. Frederick said years later about the vote, "We resolved to change the community, we narrowly won." He was a seeker of justice and a natural leader who was assertive when pushing for what he believed in.

For his lifetime of service, C. Frederick was inducted into the National Bar Association Hall of Fame. Other organizations that have honored him include the Mallory, Van Dyne and Scott Bar Association, the Genesee Bar Association, and the NAACP. He has served as an Executive Board Member of the NAACP, President of the Community Civil League, was a founder and President of the Urban Coalition of Flint. He was a member of Christ Fellowship Baptist Church, a life member of the Flint