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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 funds 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, eg., 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 USTPO 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 USTPO 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 USTPO'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 parthenogensis; 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 stem 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 patenable subject matter under 35 U.S.C. Section 101. In 1980, the US 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 provision's 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 1987 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 USC 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 nonstatutory subject matter*."

NOTE: the USPTO's Karen Hauda also testified on Thursday June 20, 2002 before the President's Council on Bioethics, "The Current policy of the USPTO is to consider any claim encompassing a human being at any stage of development, and not to be patent eligible subject matter under 35 U.S.C. 101."

- Claims directed to human beings, that is, human organisms, at any stage of development are not patentable subject matter under U.S. patent law. Funds under the CJS Appropriations prevent the USPTO from issuing patents on claims directed to human organisms.

- Patent Reform legislation that would allow the USPTO to issue patents using funds not appropriated under the CJS appropriations bill will bypass the Weldon patent ban.

- To maintain the U.S. policy against patenting humans, patent reform legislation must codify the Weldon Amendment to prevent the patenting of humans.