

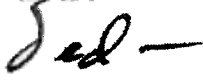


UNITED STATES PATENT AND TRADEMARK OFFICE

UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND
DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE

NOV 20 2003

The Honorable Ted Stevens
Chairman, Committee on Appropriations
United States Senate
Washington, DC 20510-6025

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

cc: The Honorable Robert C. Byrd
The Honorable Judd Gregg
The Honorable Ernest F. Hollings