MEMORANDUM

DATE: September 20, 2011

TO: Patent Examining Corps

FROM: Robert W. Bahr
       Senior Patent Counsel
       Acting Associate Commissioner
       for Patent Examination Policy

SUBJECT: Claims Directed to or Encompassing a Human Organism

Section 33(a) of the Leahy-Smith America Invents Act states: "Notwithstanding any other provision of law, no patent may issue on a claim directed to or encompassing a human organism."

This provision of the Leahy-Smith America Invents Act does not change existing law or long-standing USPTO policy that a claim encompassing a human being is not patentable. *See Animals - Patentability, 1077 Off. Gaz. Pat. Office 24 (April 21, 1987)* (indicating that human organisms are excluded from the scope of patentable subject matter under 35 U.S.C. 101). This long-standing policy is reflected in MPEP § 2105, which currently provides that:

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.

Thus, section 33(a) of the Leahy-Smith America Invents Act codifies existing USPTO policy that human organisms are not patent-eligible subject matter.

The USPTO is providing a new form paragraph (7.04.01) for use in rejecting claim(s) directed to or encompassing a human organism to reflect that such claim(s) are not permitted under either 35 U.S.C. 101 or section 33(a) of the America Invents Act.

Form Paragraph

7.04.01 Human Organism

Section 33(a) of the America Invents Act reads as follows:

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

Examiner Notes

1. This paragraph must be preceded by form paragraph 7.04 which quotes 35 U.S.C. 101.

2. In bracket [1], pluralize "Claim" if necessary, insert claim number(s), and insert "is" or "are" as appropriate.

3. In bracket [2], explain why the claim is interpreted to read on a human organism.