




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.

Claim [1] rejected under 35 U.S.C. 101 and section 33(a) of the America Invents Act as being directed to or encompassing a human organism. *See also 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). [2]

#### 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.