

U.S. Patent and Trademark Office, "Notice: Animals—Patentability," 1077 Official Gazette U.S. Pat. and Trademark Off. 8 (April 21, 1987):

"The Patent and Trademark Office now considers non-naturally 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. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. Accordingly, it is suggested 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."

(This notice responded to the Supreme Court's 1980 decision in *Chakrabarty* concluding that a modified "microorganism," a bacterium, could be patented, and a subsequent decision by the USPTO's own Board of Appeals in *Ex parte Allen* that a multicellular organism such as a modified oyster is therefore patentable as well. The USPTO sought to ensure that these policy conclusions would not be misconstrued as allowing a patent on a human organism.)

U.S. Patent and Trademark Office, Manual of Patent Examining Procedure (Revised February 2003), Sec. 2105: "Patentable Subject Matter—Living Subject Matter":

"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."

In other words, the USPTO clearly distinguishes between organisms that are nonhuman and therefore are patentable and those organisms that are human and therefore not patentable subject matter.

As a USPTO official testified recently to the President's Council on Bioethics:

"When a patent claim includes or covers a human being, the USPTO rejects the claim on the grounds that it is directed to non-statutory subject matter. When examining a patent application, a patent examiner must construe the claim presented as broadly as is reasonable in light of the application's specification. If the examiner determines that a claim is directed to a human being at any stage of development as a product, the examiner rejects the claims on the grounds that it includes non-statutory subject matter and provides the applicant with an explanation. The examiner will typically advise the applicant that a claim amendment adding the qualifier, non-human, is needed, pursuant to the instructions of MPEP 2105. The MPEP does not expressly address claims directed to a human embryo. In practice, examiners treat such claims as directed to a human being and reject the claims as directed to non-statutory subject matter." (Testimony of Karen Hauda on behalf of USPTO to the President's Council on Bioethics, June 20, 2002, <http://bioethicsprint.bioethics.gov/transcripts/jun02/june21 session5.html>)

Current USPTO policy, then, is that any claim that can reasonably be interpreted as "directed to" or "encompassing" a human being, and any claim reaching beyond "nonhuman" organisms to cover human organisms (including human embryos), must be re-

jected. My amendment simply restates this policy, providing congressional support so that federal courts will not invalidate the USPTO policy as going beyond the policy of Congress (as they invalidated the earlier USPTO policy against patenting living organisms in general).

Literally the only difference between my amendment and some of these USPTO documents is that the amendment uses the term "human organism," while the USPTO usually speaks of the non-patentability of (anything that can be broadly construed as) a "human being." But "human organism" is more politically neutral and more precise, having a long history of clear interpretation in federal law.

Since 1996, Congress has annually approved a rider to the Labor/HHS appropriations bill that prohibits federal funding of research in which human embryos are created or destroyed—and this rider defines a human embryo as a "human organism" not already protected by older federal regulations on fetal research. In December 1998 testimony before the Senate Appropriations Subcommittee on Labor/HHS/Education, a wide array of expert witnesses—including NIH Director Harold Varmus and the head of a leading company in BIO—testified that this rider does not forbid funding research on embryonic stem cells, because a human embryo is an "organism" but a stem cell clearly is not (see S. Hrg. 105-939, December 2, 1998). That same conclusion was later reached by HHS general counsel Harriet Rabb, in arguing that the Clinton administration's guidelines on stem cell research were in accord with statutory law; this same legal opinion was accepted by the Bush administration when it issued its more limited guidelines for funding stem cell research (Legal memorandum of HHS general counsel Harriet S. Rabb, "Federal Funding for Research Involving Human Pluripotent Stem Cells," January 15, 1999). To argue now that a ban on patenting "human organisms" somehow bans patenting of stem cells or stem cell lines would run counter to five years of legal history, and would undermine the legal validity of any federal funding for embryonic stem cell research.

BIO also claims that the amendment raises new and difficult questions about "mixing" animal and human species. What about an animal that is modified to include a few human genes so it can produce a human protein or antibody? What about a human/animal "chimera" (an embryo that is half human, half animal)? The fact is, these questions are not new. The USPTO has already granted patents on the former (see U.S. patent nos. 5,625,126 and 5,602,306). It has also thus far rejected patents on the latter, the half-human embryo (see Biotechnology Law Report, July-August 1998, p. 256), because the latter can broadly but reasonably be construed as a human organism. The Weldon amendment does nothing to change this, but leaves the USPTO free to address new or borderline issues on the same case-by-case basis as it already does.

In short, my amendment has exactly the same scope as the current USPTO policy, and cannot be charged with the radical expansions of policy that BIO and its allies claim. In reality, BIO opposes this amendment because it opposes the current USPTO policy as well, and has a better chance of nullifying this policy in court (or having courts reinterpret it into uselessness) if it lacks explicit support in statutory law.

This goal is apparent from BIO's own "fact sheet" opposing the amendment (see www.bio.org/ip/cloningfactsheet.asp). There BIO argues that human beings should be patentable, if they arise from anything other than "conventional reproduction" or have any "physical characteristics resulting from human intervention." In other words, humans should be seen as "inventions" and thus be patentable on exactly the same grounds as animals are now.

The logic of this argument reaches beyond the human embryo, because an embryo who resulted from reproductive technology or received any physical or genetic modification presumably remains just as invented throughout his or her existence, no matter what stage of development he or she reaches.

BIO's stated support for reducing members of the human species to patentable commodities makes the passage of my amendment more urgently necessary than ever.

CONGRATULATIONS TO CHARLES
E. KRUSE, DISTINGUISHED
EAGLE SCOUT

HON. IKE SKELTON

OF MISSOURI

IN THE HOUSE OF REPRESENTATIVES

Wednesday, November 5, 2003

Mr. SKELTON. Mr. Speaker, it has come to my attention that my good friend, Charles E. (Charlie) Kruse, President of the Missouri Farm Bureau Federation, has been named as the next recipient of the Distinguished Eagle Scout Award. As an Eagle Scout myself, let me take this means to pay tribute to Charlie for reaching this important milestone.

The Distinguished Eagle Scout Award (DESA) was established in 1969. It is granted to Eagle Scouts who received the Eagle Scout rank 25 or more years ago and who have distinguished themselves in their professional life and in their communities on a voluntary basis. The award is granted by the National Eagle Scout Association upon nomination by a local council and selection by a committee of nationally prominent DESA recipients.

In his personal and professional life, Charlie Kruse has established himself as a true role model for patriotic Americans. His life work has far exceeded the guidelines established for receiving this respected award. He has served the American people and the residents of Missouri in the military, as a member of the Governor's cabinet, on the Missouri University Board of Curators, and on many national commissions and boards. He has also worked to enhance the prosperity of his community through church and volunteer activities.

Charlie currently serves as President of the Missouri Farm Bureau Federation. In his role, he represents over 100,000 Missourians and provides Members of Congress from the Show-Me State with useful information about what farmers and ranchers are saying about U.S. agricultural policy. Farm Bureau's advice is critical to shaping a national agricultural agenda in a way that benefits Missourians, and I appreciate hearing from Charlie and all Farm Bureau members.

Mr. Speaker, I know that all my House colleagues will join me in paying tribute to Charlie Kruse as he receives the Distinguished Eagle Scout Award. He truly deserves this recognition.