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A Production Ethic for the 21st Century

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* A Project of the Center for Respect of Life and Environment and The Humane Society of the United States

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Commissioner of Patents and Trademarks
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Attn: Stephen Walsh

Dear Mr. Walsh

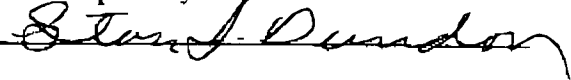
Although I am national Coordinator of the Soul of Agriculture Project (see www.soulofag.org) I am writing this note as a private citizen and teacher (at California State University, Sacramento) of business and computer ethics. I am writing in response to the Patent and Trademark Office Request for Comments on the Revised Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112 para. 1 "Written Description" Requirement as published in the Federal Register on December 21, 1999. I support the views of the Council for Responsible Genetics (CRG) as described below. I believe the PTO should further amend the revised Guidelines before they are made final.

But in addition to the views laid out below, I would add the following: The clear intent of patent protection in general and "intellectual property" in particular is to promote useful invention and the economic/social progress that that creative activity provides. Much of the patent activity in genetic materials is really aimed at pre-emptive sequestering of objects of whole natural origin with a view of locking out its use by other persons who may have some creative and beneficial use in mind. If the "discoverers" of this genetic object were actually engaged in making some application of this genetic material, they could patent that application, leaving the genetic object free for examination and application by other true inventors.

It should be clear that this pre-emptive sequestering retards rather than promotes creative activity. Court decisions with respect to computer coding have made this very point, and there the code segments were actually devised by human inventiveness rather than merely discovered in nature. Traditional industry-wide code elements, even if some one can show they first devised them, are not allowed to be patented, anymore than could the person who could prove he/she first set up the 2"x4" standard for wall-studs claim that all users of 2"x4"s should pay a license fee. Clearly genetic codes are even more universally in use, even if recognized only in their impacts on the phenotypes.

The CRG notes that US patent law excludes "Products of nature" from patentable subject matter [35 USC 112; *Diamond v Chakrabarty* 100 S. Ct 2204, 2206]. We further note "The 'essential goal' of the description of the invention requirement is to clearly convey the information that an applicant has invented the subject matter which is claimed". One of the great advances of modern biology has been the recognition that the genetic material of an individual is inherited from previous generations. Our genes are derived from our parents, grandparents, and their progenitors through the germline. It is clear that human genes are products of nature. It therefore seems that to be considered an "invention" the written description of a gene patent claim would have to establish that the sequence does not occur in any known organism. Patent Office Guidelines should therefore instruct examiners clearly that any descriptions which claim that the sequences to be patented are present in the human genome, should be denied, since there would be no inventive step. Such sequences may be accurately described as 'discovery', but not 'invention'. The patent office may receive applications for nucleic acid sequences that are claimed to be truly invented. In fact only a tiny fraction of the genomes of the hundreds of thousands of animals, plants and microorganisms species have had their gene sequences determined. It is therefore not possible at the present time to ascertain that any nucleic acid sequence is an invention. The prudent course would therefore be to request clarification from the U.S. Congress as to whether gene sequences do indeed fall in the realm of patentable inventions. We note that the Supreme Court in the *Chakrabarty* decisions did not identify genes as patentable subject matter, but rather a reproducing and metabolically active genetically modified micro-organism [*Diamond v. Chakrabarty*, 100 S.Ct], thus implying the distinction between natural genes and their inventive application which I made above.

Respectfully submitted



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