Comment 57 Council for Responsible Genetics / Claire Nader

Box 8, Commissioner of Patents and Trademarks
Washington, D.C. 20231
Attn: Stephen Walsh
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March 20, 2000

Dear Mr. Walsh

We are 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.

We are writing on behalf of the Council for Responsible Genetics, 5 Upland Road, Cambridge, MA 02140 a national non-profit organization with offices in Cambridge, Mass. We publish a national newsletter Genewatch which represents public interests in issues of genetic technology and biotechnology. We also represent the interests of thousands of citizens who have signed our petition entitled "No Patents on Life" which can be read at our website: www.gene-watch.org. The comments below represent the views of our organization.

We believe the PTO should further amend the revised guidelines before they are made final.

We note 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 decision 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].

We therefore believe that the tradition established for almost 200 years since Thomas Jefferson supervised the writing of the original Patent Acts, remains valid. Patent examiners should be instructed to reject patent claims whose written descriptions describe nucleic acid sequences derived from organisms.

Patents previously granted for gene sequences under the flawed written description guidelines may have to be re-examined.

Respectfully submitted,

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