

>Commissioner of Patents and Trademarks
>Box 8, Washington, D.C. 20231
>Attn: Stephen Walsh
>FAX 703 305 9373
>stephen.walsh@uspto.gov

Dear Mr. Walsh,

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> 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 am writing as a concerned citizen. My name is Frances Oliver and I
reside at

>2478 Windbreak Drive, Alexandria, VA 22306.

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.

> 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]. It further notes "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. The CRG notes 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].
- > The CRG therefore believes 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 described nucleic acid sequences derived from
- >organisms.
- > Patents previously granted for gene sequences under the flawed written
- >description guidelines may have to be re-examined.

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Respectfully submitted,
Frances Oliver