The 1998 edition: Our Bodies, Ourselves for the New Century

inspiring a movement of women's health around the world

BOSTON WOMEN'S HEALTH BOOK COLLECTIVE

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A Member Agency of Community Works

March 22, 2000

Stephen Walsh
Office of the Commissioner of Patents and Trademarks
Box 8, Washington, D.C. 20231
VIA FACSIMILE: 703 305 9373

Dear Mr. Walsh:

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.

The Boston Women's Health Book Collective supports the views of the Council for Responsible Genetics (CRG) as described below. We 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]. 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].

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 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.

Sincerely,

Anna M. Pohl
Program Assistant