Comment 24 Jonathan King

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

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.

My name is Jonathan King and I am Professor of Molecular Biology at the Massdachusetts Institute of Technology. I reside at 40 Essex Street, Cambridge, MA 02139. I am a co- auther of more than 100 scientific papers on the genetic control of protein structure and assembly. I have served as an officer of national and international scientific societies,and as an expert witenss in biotechnology patent litigation. I am writing as a concerned citizen and a professional scientist who has spent my professional life carrying out research in molecular genetics and biochemistry financed by the taxpayers of the United States through the National Institutes of Health and National Science Foundation.

I believe the PTO should further amend the revised Guidelines before they are made final. My arguments share elements in common with those submitted by the Council for Responsible Genetics, a leading advocacy organization for protecting the public's interest in our genetic heritage.

US patent law excludes "Products of nature" from patentable subject matter [35 USC 112; Diamond v Chakrabarty 100 S. Ct 2204, 2206]. Thus minerals and other "Phenomena of nature, though just discovered, ... are not patentable....." Parker v. Flook, 198 USPQ 193 (1978).

I note that "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 central tenets of modern genetics is the recognition that the genes and gneomes of individuals are inherited from previous generations. Our genes are derived from our parents, grandparents, and their progenitors through the germline. It is therefore clear that human genes are products of nature. Though unique variants may be geneated by recombination and mutation, these events happen during the development of the germ cells in the parental generation. Therefore 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. Discovering the order of the nucleotides in an existing gene

constitutes discovery, but not invention.

Patent Office Guidelines should therefore instruct examiners clearly that any descriptions which claim that the sequences to be patented are present in human, animal, lant or microbial genomes, should be denied, since there would be no inventive step. An noted, such sequences may be accurately described as 'discovery', but this does not constitute an inventive step.

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.

Respectfully submitted,

Jonathan King

Jonathan King
Prof. of Molecular Biology
MIT
68-330
Cambridge, MA 02139
617-253-4700
FAX 617-252-1843
