Comment 20 Bill Freese

Commissioner of Patents and Trademarks
Box 8
Washington, DC 20231
Attn: Stephen Walsh

RE: USPTO Request for Comments on the Revised Interim Guidelines for Examination of Patent Applications under 35 U.S.C. 112, par. 1 "Written Description" requirement as published in the Federal Register of December 21, 1999

Dear Mr. Walsh,

My name is Bill Freese, and I reside at 3206 Shepherd St., Mt. Rainier, MD 20712. I am commenting as a concerned citizen.

I support the position of the Council for Responsible Genetics (CRG), as detailed below. The PTO should further amend the revised Guidelines before they are made final.

US patent law excludes "products of nature" from the category of patentable subject matter [35 USC 112; Diamond v. Chakrabarty 100 S. Ct 2204, 2206]. In addition, the law states 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 great discoveries of the science of genetics is that an individual's genetic information is inherited from previous generations. Our genes are passed down from parents, grandparents and their progenitors through the germline. It is indisputable that human genes are products of nature. As such, they are in no sense "inventions." Neither can the nucleic acid sequence characteristic of any given human gene be considered an invention. The determination of such a sequence is properly understood as a discovery of certain properties of a product of nature.

Therefore, patent office guidelines should instruct examiners to deny any descriptions which claim as inventions nucleic acid sequences discovered in nature. There is no inventive step in such a discovery. Neither should the nucleic acid sequence of an artificially modified gene not found in nature be considered an invention. In this case as well, the major inventive step has been carried out by nature, not man.

The prudent course would be to request clarification from Congress as to whether gene sequences do indeed fall in the realm of patentable inventions.

Please note that in the Chakrabarty decisions, the Supreme Court did not identify genes as patentable subject matter, but rather a reproducing and metabolically active genetically modified microorganism [Diamond v. Chakrabarty, 100 S. C.].

The tradition established almost 200 years ago by Thomas Jefferson as he 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 living beings. Patents previously granted for gene sequences under the flawed written description guidelines should also have to be reexamined.

Sincerely yours,
Bill Freese