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From: John James [SMTP:j.james@sympatico.ca]
Sent: Monday, March 20, 2000 8:35 PM
To: linda.therkorn@uspto.gov
Subject: Comments on the Revised Interim Guidelines

Dear Mr. Nagumo/Ms. Therkorn:

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. 101 para. 1 "Utility" requirement, as published in the Federal Register on December 21, 1999.

I am writing as a concerned citizen. My name is John James and I reside in Canada. I agree substantially with the opinion of the Indigenous Peoples Council on Biocolonialism as described below.

I believe the PTO should further amend the revised guidelines. U.S. patent law excludes "products of nature" from patentable subject matter. One of the most basic tenets of modern western biology is 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 the products of nature.

It therefore seems that, in order to be considered the proper subject of patents-- an "invention," a patent claim for genetic sequences would have to establish that the sequence does not occur in any known organism. The Patent Office Guidelines should therefore instruct examiners clearly that any patent applications which claim that the sequences to be patented are present in the human genome should be denied, since there is no inventive step in merely describing what already exists in nature. While descriptions of such sequences might be accurately defined as "discovery," they are clearly not an "invention."

Further, under existing patent law, patents cannot be granted for something which is "prior art". Applying for a patent would require the applicant to prove that no prior knowledge of that use existed among any community in order to meet the prior art requirement. This would require the applicant to prove that no cultural knowledge of that use existed prior to the discovery or invention for which the patent is sought.

The Patent and Trademark Office may receive claims for nucleic acid sequences that are claimed to be truly invented. In fact only a tiny fraction of the genomes of the many different species of animals and plants have had their genetic 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 be for the Patent and Trademark Office to seek clarification from Congress on whether naturally occurring genetic sequences are properly subject to the patenting system. 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). In the interim, Patent examiners should be instructed to reject patent claims whose written descriptions describe nucleic acid sequences derived from organism.

The extension of patents to genetic sequences is a profound misuse of the patent system and represents the privatization, only to support corporate interests, of something that is not an invention and should not be subject to corporate ownership. No individual, institution, or corporation should be able to claim ownership over species or varieties of organisms.

Sincerely,

John James