

>>Commissioner of Patents and Trademarks

>>Box 8, Washington, D.C. 20231

>>Attn: Stephen Walsh

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>>

>>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.

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>> I am writing as a concerned citizen. My name is Donald Sawyer and I  
reside in Brasilia, Brasil.

>> 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]. 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  
>>aspects 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.

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>>Respectfully submitted,

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>>Donald Sawyer