

## Comment 25 Christian Lacoste

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.

> I am writing as a concerned citizen. My name is Christian Lacoste and  
> 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,  
>Christian Lacoste