Comment 27 Rod Leonard

>Commissioner of Patents and Trademarks
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>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.
> I am writing as a concerned citizen. 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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