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Box 8
Commissioner of Patents and Trademarks
USPTO Office of Initial Patent Examination
Crystal Plaza Building 2, Room 1B03
2011 South Clark Place
Arlington, VA 22202

Attn: Mark Nagumo

RE: * Revised Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112 "Written Description" Requirement (64 FR 71427)

*Revised Interim Utility Examination Guidelines (64 FR 71440)

I am writing as the President of the American College of Medical Genetics (ACMG), representing over 1,100 clinical and laboratory geneticists in the U.S. These include doctoral trained clinical geneticists, as well as molecular, biochemical and cytogenetics laboratory directors certified by the only specialty level board of the American Board of Medical Specialties (ABMS) in this field, the American Board of Medical Genetics (ABMG). Our members are involved in clinical genetics and genetic research and the translation of genomic knowledge into clinical services, as well as providing genetics laboratory services considered standard of care in the field. I am writing in response to the above guidelines that appeared in the Federal Register on December 21, 1999.

The members of the ACMG are deeply concerned about the patenting of human genes and fragments, and the enforcement strategies of sequence patent holders and licensees, which are limiting public access

to important clinical services. Indeed, we have difficulty understanding of how or why patent law has been interpreted to permit naturally occurring sequences, which are uniquely fundamental information to be patented. Such a view has led to patenting of discoveries rather than inventions. However, our comments today are directed at the "Revised Interim Utility Examination Guidelines" and the "Written Description Requirement".

Initially, we commend the Patent and Trademark Office (PTO) for recognizing the need to raise considerably the utility requirements by which determinations of patentability are made. We strongly oppose patents for gene fragments such as expressed sequence tags (ESTs), sequence tagged sites (STSs) and, more recently, single nucleotide polymorphisms (SNPs). These fragments are of use only in the search for complete genes and, as such, are research tools which should be widely available and accessible and not encumbered by patents. We also appreciate the proposal to enhance the requirements for specific, substantial and credible utility claims.

In order to more fully understand our concerns, it is important to recognize the rapid pace at which this field is moving and the speed at which new knowledge renders previous knowledge obsolete. Our members have been at the forefront of the development of gene mapping and genetic technology for the past 40 years thus, we have a unique investment in this issue. Our specific comments on the utility and written description proposal follow.

Revised Utility Guidelines: ACMG believes that there must be specific, substantial, and credible claims for utility. We do not believe that presumed theoretical function based on homology searches is sufficient to claim specific and substantial utility. Frequently, genes have numerous functional domains and knowledge of one or a few can be misleading or incorrect as to the actual role of the gene in question. As such, gene sequences are merely research tools, which ultimately allow for determinations of actual function and, thereby, the invention, to be made; however, the tools are <u>not</u>, themselves, inventions. Unfortunately, thousands of patents are pending for sequences whose presumed function is based on little more than computer searches of regions of homology and we do not believe that such blind searches, lacking both creativity and scientific knowledge, should lead to patentable material. It is noteworthy that such "research" is no longer considered worthy of doctoral level degree awards since there is virtually no novelty involved in such projects.

The PTO must decide the criteria to be used to determine whether or not a DNA sequence meets the standard for specific, substantial and credible utility. The ACMG

agrees with the NIH (as expressed in a letter of December 21, 1999 from Drs. Varmus and Collins to Commissioner Dickenson) that the revised standard should not be interpreted to embrace claims of a "predicted" function for a gene or its encoded protein, based only on sequence homology with other proteins and genes.

Among those practicing in this area, views of substantial, specific and credible utility change on a weekly basis. This is not surprising given the enormous international investment in genomics. It will be important that the PTO remain apace with the sense of those skilled in this art to avoid a morass of competing claims and the cross-licensing nightmare of our time.

Written Description Guidelines: Our concerns with the descriptions of the patented entity are focused on claims language, which generalizes the claims in order to broaden their scope. These claims should be dealt with in a manner similar to that for chemicals. As such, the descriptions should include complete and unaltered sequence information and claims should not extend beyond that described. Recognition of overbroad claims for gene or genomic fragments would lead to yet another morass of competing claims against those who perform the actual science required to state a complete gene sequence. Those with claims on partial sequence information as is the case for ESTs and other fragments should not be able to exercise superiority over the full gene sequence patent holder.

We appreciate the opportunity to comment on the proposed changes to the review of gene patent claims and agree that such claims should be based on thorough understanding of the structure and function of the claimed sequence. We recognize the great responsibility that the Patent and Trademark Office has in ensuring intellectual property protection for inventions involving gene-based discoveries. We are pleased that the PTO is considering changes to its guidelines and we hope that the feedback from our group, and others in the scientific community, will be helpful in developing new guidelines. Please let us know if our group can be of further assistance in this important project.

Sincerely,

R. Rodney Howell, M.D.
President