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NOV 23 1998
U.S. PATENT & TRADEMARK OFFICE

OFFICE OF TECHNOLOGY TRANSFER
1111 Franklin Street, 5th Floor
Oakland, California 94607-5200
Web Site: www.ucop.edu/ott/
Tel: (510) 587-6000
Fax: (510) 587-6090

November 11, 1998

Mr. Scott A. Chambers
Associate Solicitor
Commissioner of Patents and Trademarks
Box 8
Washington, DC 20231

Re: Comments on Interim Guidelines for Examination of Patent Applications
Under the 35 U.S.C. 112, Paragraph 1 "Written Description" Requirement

Dear Mr. Chambers:

This comment on behalf of the University of California responds to the June 15, 1998 notice at 63 Federal Register 32639 and the September 23, 1998 extension notice at 63 Federal Register 50887 for comments on the Interim Guidelines for Examination of Patent Applications. Under the 35 U.S.C. 112 Paragraph 1 "Written Description" Requirement. Thank you for the opportunity to comment in this extended period.

The purpose of this letter is to respond to the September 23, 1998 extension notice Issues for comment number 11: "Are there additional issues related to other statutory requirements of Title 35 invoked in the patenting of ESTs?" More particularly, this comment supports the general theme set forth by the National Institute of Health in its comments under this notice that the patentability of claims that encompass full-length cDNAs or genes should be dependent on an actual functional utility being known to the inventor rather than simply that one can use the disclosed DNA sequence as a probe for other DNA from the same or similar source. Sufficient patentable utility is not shown when a gene fragment's only known use is to identify other nucleic acids whose utility is also not known. Genes and gene fragments can have a practical functional utility, for example, in diagnostic assays, but until an actual, functional utility is known, it is submitted that a patent does not meet the requirements of 35 U.S.C. 101 utility.

Article I, Section 8, Clause 8 of the U.S. Constitution provides a policy for the patent system "to promote the progress of science and the useful arts." Issuing a patent to an "inventor" who does not know any practical utility makes later use of the claimed DNA composition of matter subject to injunction or royalty obligation to the detriment of later discoverers of a practical utility. That legal burden could be enough to chill later development of the invention, especially in the life

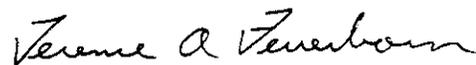
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sciences where commercialization often requires large investments over a long time period. When the function of a DNA sequence, whether of a full length gene or a subsequence is known, it should be the subject of possible patent protection just like any other invention. DNA fragments or sections of a genome where an actual function is not known should not be the subject of patent protection.

With respect to the newly restrictive written description requirement in response to The Regents of the University of California v. Eli Lilly 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) it is submitted that there is no statutory basis for discrimination in patentability against DNA-based inventions versus other chemical inventions. In that case, the University had complete sequence information in 1977 for one species, rat proinsulin, and promptly filed a patent application with species and genus claims, reflecting that significance of the discovery. The specification described how one could follow the already proven method to reveal other DNA sequences species for proinsulin. This logic was the basis for the U.S. Patent and Trademark Office ("USPTO") rejection of the second patent in the case, filed in 1979, until a further limitation was placed on the claims to human proinsulin DNA. It was the consistent position of the USPTO in the prosecution of the 1977 and the 1979 patent applications that the University's inventors were in possession of the invention covered in the genus claims in the 1977 filing. The USPTO was right the first time and the second time. It is urged that the USPTO not let one ill-advised court decision disadvantage an entire industry through the issuance of broad guidelines based on that decision, especially for a technology as important to the nation as a healthy biotechnology sector.

Thank you for this opportunity to comment.

Sincerely,



Terence A. Feuerborn
Executive Director
Research Administration and
Technology Transfer