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November 12, 1998

Box 8
Commissioner of Patents and Trademarks
Washington, D.C. 20231

Attn: Scott A. Chambers
Associate Solicitor

Dear Solicitor Chambers:

The following are the comments of Monsanto Company, St. Louis, Missouri, on the written description guidelines published in the Federal Register, Vol. 63, No. 114, pages 32639 et seq. Monsanto is a publicly traded "life science" company doing research in the areas of pharmaceuticals, agriculture and nutrition. Monsanto also has as substantial investment in the research area known as genomics.

Monsanto's comments are particularly directed to questions 10 and 11 found in the Federal Register, Vol. 63, No. 184, page 50888. Those questions address the patentability of expressed sequence tags (ESTs).

It is Monsanto's position that applications directed to ESTs, where the application only discloses ESTs and does not disclose specific functions to the ESTs other than functions generally applicable to any EST, should not be entitled to claims reading upon genes.

It is believed by Monsanto that current law and current case law support the above position as described below.

An application directed to ESTs without any specific functional information, except that applicable to any EST, does not meet the utility requirement under 35 U.S.C. § 101. The Supreme Court in *Brenner v. Manson* is generally believed to have held that an invention who's sole utility is in conducting research is not a sufficient utility under the patent laws. The Supreme Court stated:

"A patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion. A patent system must be related to the world of commerce rather than to the realm of philosophy. . ." 148 U.S.P.Q. 689, 696 (1966)
See also *In re Joly* and *In re Kirk*.

Page 2

Commissioner of Patents and Trademarks

November 12, 1998

Commissioner Bruce Lehman in a letter to Dr. Harold Varmus, Director of the NIH, has apparently agreed with this position. In the letter, the Commissioner stated:

Mere allegation of the utility of an EST as a probe without further disclosure is not sufficient to meet the utility and enablement criteria. Example 9, in our training materials for the Patent Utility Guidelines, outlines a DNA probe, which lacks utility because no utility for the protein corresponding to the cDNA identified by the probe or for the cDNA itself, was disclosed. A copy of Example 9, setting forth the Patent Utility Guidelines, has been enclosed for your convenience.

April 2, 1997 letter from Lehman to Varmus.

Our preference would be for a clarification statement from the USPTO that unless an EST is described in the application as having in and of itself a utility other than as a research tool, that they be held not to have sufficient utility to support patentability.

An application directed to an EST with no function attributed to the EST other than the function existing for all ESTs also does not provide an enabling disclosure for a claim encompassing a gene. The courts have provided the test for whether an invention is enabled in *Ex parte Forman* and repeated them in *In re Wands*, 8 USPQ2D 1400 (Fed. Cir. 1988). While these factors should be considered on a case by case basis, many EST applications do not enable one skilled in the art to use the full length gene or related sequences. If not enabled, then such genes or sequences should not be claimed or embraced by a claim.

An application containing such information also does not have a written description of a gene. Written description is a requirement that the inventor demonstrate "possession" of the invention. In *Fiers vs. Revel*, the Federal Circuit created a rule that one cannot have possession of a DNA sequence until one knows the DNA sequence or at least has enough knowledge about the sequence to uniquely describe it. This rule can be essentially circumvented if one can have claims that encompass a full length gene on the basis of only an EST. The written description guidelines published in the Federal Register properly require information as to size of the gene, function of the gene, and other information related to the gene to claim the gene. It is respectfully submitted that such information is necessary to write a claim that encompasses the gene as well.

The guidelines unfortunately confuse this requirement by stating that a written description of a DNA sequence is sufficient to permit a claim encompassing the full length gene even though the same "written description" is not sufficient to write a specific claim to that gene. If there is not sufficient description to write a specific claim to a particular subject matter, then there likewise should not be sufficient description to write a claim encompassing the subject matter.

Page 3
Commissioner of Patents and Trademarks
November 12, 1998

Monsanto would like to thank the PTO for the opportunity to comment on these guidelines.

Respectfully submitted,



Richard H. Shear
Associate General Counsel, Intellectual Property

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