From: Joy Mulholland [mailto:jmulholland@ratnerprestia.com]
Sent: Tuesday, October 06, 2009 10:18 AM
To: Fawcett, Susan
Subject: A0651-0024 comment @

Dear Ms Fawcett,

Below please find our comments with respect to sequence disclosures. These remarks reflect the opinions of a group of biotech attorneys and are not to be interpreted as representing the opinion of the law firm listed below.

Joy Mulholland, Ph.D.

Response to Section IV. Request for Comments on Requirements for Patent Applications Containing Nuceotide Seuqence and/or Amino Acid Sequence Disclosures

(a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information hshall have practical utility.

Response:

The information has utility as to the sequence. The listed sequence is used by the patent examiner for comparison with sequence databases to determine novelty.

The additionally requested information, such as name of organism and repetition of client identification and inventor names is not necessary.

(b) The accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information.

Response:

The estimate of time required to prepare a sequence listing is much too low. We estimate the usual time as between 1 and 5 hours.

The estimated costs are based on preparation of the sequence listing by a paraprofessional. Attorneys are preparing sequence listings in many firms, especially boutique and solo practice firms. Therefore, the estimated costs of preparation are probably much too low.

A great deal of time is spent complying with minutiae, and then complying with notices to correct mistakes made while trying to glean the correct way to describe a sequence from the tables in Rule 823.

(c) Ways to enhance the quality , utility, and clarity of the information to be collected

Response:

Provide a clearer explanation of the sequence rules and instructions for how to list the required information. Provide examples for unusual situations such as skipping a sequence number.

Develop a less tedious program for preparing sequence listings. PatentIn is very inefficient. Program should accept both three and one letter amino acid codes.

(d) Ways to minimize the burden of the collection of information on respondents.

Response:

Require sequence listings only for sequences that are actually claimed or are substantially likely to be claimed. Currently it is necessary to list any sequence mentioned in the specification having ten or more nucleotides or four or more amino acids. This may include known sequences, sequences unrelated to the invention, artificial primer sequences and nonsense sequences used as experimental controls.

Remove the requirement for information other than the sequence itself. All of this information adds to the page count.

Do away with the requirement for a statement that the paper copy and electronic copy of the sequence listing are identical. Electronic filing may put an end to this eventually, but, in the meantime, a checkbox could be added to the transmittal sheet in lieu of a separate paper statement.

Make the sequence listing part of the specification instead of requiring a preliminary amendment or incorporation by reference.

Provide an easier way to list unual amino acids or nucleotides. Provide a usable code for the most common alternative amino acids and nucleotides, e.g., ornithine, norvaline.

Provide a better software program to prepare sequence listings. Program should accept both three and one letter amino acid codes.

Provide a clearer explanation of the sequence rules and instructions for how to list the required information.

Have the patent examiner explain to applicants how to fix whatever is wrong with the sequence listing. If it is something simple, have the examiner fix it by examiner's amendment.

Offer a service for preparation of sequence listings at a reasonable fee.

Joy Mulholland, Ph.D.
RatnerPrestia
(Mailing Address)
P.O. Box 980
Valley Forge, PA 19482
OR
(Street Address)
1235 Westlakes Drive
Suite 301
Berwyn, PA 19312
phone: 610-993-4237
fax: 610-407-0701
e-mail: jmulholland@ratnerprestia.com
WE SPECIALIZE IN THE LAW OF CREATIVITY