From: Robin Muthig
Sent: Monday, July 16, 2012 3:22 PM
To: seq_listing_xml
Cc: Herbert C. Wamsley; Vanessa Pierce Rollins
Subject: IPO Comments on 77 Fed. Reg. 94

Please see attached comments from Intellectual Property Owners Association in response to 77 Fed. Reg. 94 regarding "Recommendation for the Disclosure of Sequence Listings Using XML (Proposed ST.26)".

Best regards,

Robin

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July 16, 2012

Hon. David J. Kappos
Under Secretary of Commerce for Intellectual Property
and Director of the U.S. Patent and Trademark Office
600 Dulany Street
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Submitted via: seq_listing_xml@uspto.gov

Re: Comments on Proposed Rules: "Recommendation for the Disclosure of Sequence Listings Using XML (Proposed ST.26)"
77 Fed. Reg. 94 (May 15, 2012)

Dear Under Secretary Kappos:

Intellectual Property Owners Association (IPO) appreciates the opportunity to provide comments to the U.S. Patent and Trademark Office regarding the proposed changes to the rules regarding sequence listing submissions published in the Federal Register on May 15, 2012.

IPO is a trade association representing companies and individuals in all industries and fields of technology who own, or are interested in, intellectual property rights. IPO's membership includes more than 200 companies and more than 12,000 individuals who are involved in the association either through their companies or as inventor, author, law firm, or attorney members.

IPO applauds the USPTO's continuing efforts to unify the sequence listing rules with those of other countries, and to reach out to the applicant community for input regarding how to improve the ease of filing and prosecuting patent applications that contain sequence listings.

The USPTO is seeking input on the proposed changes as embodied in World Intellectual Property Organization (WIPO) Standard ST.26. Our comments are directed to that standard as published in a Final Draft dated March 28, 2012, and made available on the USPTO website.

1. General Comments on Sequence Listing Procedures

From an applicant's perspective, the preparation and submission of sequence listings can be a very difficult and time-consuming task. In many cases, the preparation must be handled by specially trained paralegals or administrative assistants due to the complexity in understanding not only the preparation software, but also the molecular biology aspects of properly defining the correct sequence information.

Thus, the ease of use of any software provided by the USPTO is of paramount importance to applicants. One of the main challenges facing applicants in submitting compliant sequence listings is understanding how to correctly use "PatentIn," or other available sequence listing software, to prepare and submit compliant sequence listings. Accordingly, IPO strongly encourages the USPTO to work closely with applicants to provide the most comprehensive, and easy to use software, when the new standard ST.26 comes into force.

Applicants regularly review their current sequence listings prior to filing in order to ensure that all of the sequences have been properly disclosed, and that the sequence numbers identified in the sequence listing properly align with sequence identifiers in the corresponding patent application. This is a fairly straightforward task under the current standard, as the sequence listing is a text document in a clear format that can be easily printed and reviewed. With the move to a more complex XML format, reviewing the sequence listing may be more challenging. Therefore, should the proposed ST.26 standard come into force, IPO encourages the USPTO to provide applicants with software functions that will easily allow them to review their sequence information in a format that is easy to read and print so applicants can confirm they are providing the USPTO with the most accurate and complete information.

2. Comment on ST.26, Paragraph 4

Paragraph 4 of proposed ST.26 defines which nucleotide and protein sequences are required to be submitted. This section changes the existing requirements by stating that sequence listings *shall not* include nucleotide sequences having fewer than 10 specifically defined nucleotides or protein sequences having fewer than four specifically defined amino acids. The current rules allow these smaller sequences to be submitted at the applicant's discretion. While IPO agrees that such short sequences should not be required to be submitted, IPO encourages the USPTO to change Paragraph 4 of the proposed rule so that sequence listings shall not include nucleotide sequences having *fewer than 25* specifically defined nucleotides.

IPO encourages the USPTO to look for ways to reduce the burden on applicants of submitting numerous short nucleotide sequences that are not the subject of the patent application claims. In many cases, biotech patent applications describe how particular genes were obtained by the inventors. It is typical for the inventors to describe the use of short nucleotide sequences of 15-20 nucleotides called "primers" to obtain their genes of interest. In many, if not most, sequence listings, the majority of sequences submitted to the USPTO are these 15-20 nucleotide primers. These primers are generally not claimed, and simply add burden to applicants to supply to the USPTO. While IPO appreciates the efforts of the USPTO to build a robust prior art database of nucleotide sequences, the burden falls on applicants to provide these unclaimed sequences, which are very likely already in the public prior art from already published patent applications, databases such as Genbank, and the well-published efforts to clone and sequence the human genome.

Changing Paragraph 4 so that sequence listings shall not include nucleotide sequences having fewer than 25 specifically defined nucleotides would remove a high burden on applicants. It would avoid the need to submit dozens, and sometimes hundreds or thousands, of primer sequences that are already available as prior art to the USPTO from a variety of sources.

3. Comment on ST.26, Paragraph 22, Sub-paragraph 1

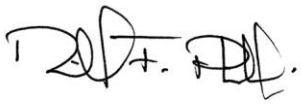
Paragraph 22, sub-paragraph 1, states that a sequence that is constructed from one or more non-contiguous segments of a larger sequence must be included in the sequence listing as a *single sequence* with a single sequence identification number. This paragraph could be in conflict with Paragraph 19, which states that amino acids separated by one or more blank spaces must be represented by multiple *separate* amino acid sequences.

In many patent applications, comparisons are shown between two amino acid sequences. In these comparisons, "gaps" or spaces are shown where a first sequence includes additional amino acids in comparison to a second amino acid sequence. Under this scenario, the second amino acid sequence is typically shown as having a gap at the position of the additional amino acid in the first sequence. According to Paragraph 19, the second amino acid sequence must be shown as being separate amino acid sequences on either side of the gap. On the other hand, according to sub-paragraph 1 of Paragraph 22, because the sequence is part of one non-contiguous segment of a larger sequence, it should be shown as a single sequence. Therefore, IPO recommends clarifying sub-paragraph 1 of Paragraph 22[1] by rewriting it to state:

> 22. A sequence disclosed by enumeration of its residues that is constructed from one or more noncontiguous segments of a larger sequence or of segments from different sequences must be included in the sequence listing as a single sequence with a single sequence identification number. <u>This single sequence would be in addition to any separate sequences shown for each of the non-contiguous segments as required under Paragraph 19.</u>

IPO thanks the USPTO for considering these comments and would welcome any further dialogue or opportunity to support the USPTO in finalizing any rules relating to proposed WIPO ST.26.

Sincerely,



Richard F. Phillips
President

[1] IPO recommends no changes to sub-paragraphs 2 and 3 of Paragraph 22.