

From: Sundby, Suzannah
Sent: Friday, July 13, 2012 9:54 AM
To: seq_listing_xml
Subject: Comments on Proposed ST.26

ATTN: Susan C. Wolski
Office of Patent Cooperation Treaty Legal Administration
Office of Associate Commissioner for Patent Examination Policy

Dear Ms. Wolski,

Thank you for this opportunity to provide comments about the Recommendation for the Disclosure of Sequence Listings Using XML (Proposed WIPO ST.26 standard), published in the Federal Register on May 15, 2012 (PTO-P-2012-2018).

I believe that the current WIPO ST.25 (ST.25) standard is sufficient for my clients' needs and types of invention. The incentives and expected benefits may make the Proposed WIPO ST.26 standard worth adopting only if such can be achieved without any added burden and cost to applicants. Unfortunately, it seems that the Proposed WIPO ST.26 standard will result in a significant burden and cost to applicants.

Specifically, the current WIPO ST.25 standard is already widely accepted in foreign countries without extra fees and little to no translation costs by foreign associates and foreign patent offices. There does not seem to be any guarantee that the Proposed WIPO ST.26 standard will be accepted in all international, regional, and national patent offices and that the XML and any additional sequence data of the Proposed WIPO ST.26 standard do not have to be translated. The Proposed WIPO ST.26 standard is expected to be about 5-10 times longer than a sequence listing under the current WIPO ST.25 standard. Thus, it seems that, in addition to foreign translation costs, extra page fees could be quite likely. Consequently, without all WIPO member countries clearly agreeing by law that the Proposed WIPO ST.26 standard will be accepted without the need for translations and extra page fees, it seems that the Proposed WIPO ST.26 standard will result in an additional burden and cost without any real benefit to applicants.

In addition, it seems the Proposed WIPO ST.26 standard requires that every permutation of a sequence having variables/substitutions is set forth. If this is true, the Proposed WIPO ST.26 standard is unduly burdensome as compared with the current ST.25 standard. Applicants are not required to set forth every possible chemical species encompassed by a general structural formula for a chemical genus. Why should there be a higher burden for applicants of inventions involving biotech sequences?

Clarification is request as to what are prohibited sequences and variants and the requirements for both under the Proposed WIPO ST.26 standard.

The requirement that all sequence variants specifically mentioned in the specification be set forth in the sequence listing as individual sequences having their own SEQ ID

NOs seems unduly burdensome. In fact, the requirement that all sequence variants disclosed in the specification only by reference to a primary sequence in the Sequence Listing (e.g., deletions, additions, or substitutions) be set forth in the Sequence Listing as individual sequences having their own SEQ ID NOs or by annotation of the primary sequence as features/qualifiers is not only unduly burdensome but will be quite costly to applicants. Specifically, it is unlikely that individuals other than the patent attorney/agent who drafted a given patent application having biotech sequences will be able to prepare the Sequence Listing for the given application as those individuals will be unfamiliar with the content of an application will not be able to readily scan the application and understand what additional variants are required to be included in the Sequence Listing under the Proposed WIPO ST.26 standard. Thus, under the Proposed WIPO ST.26 standard, the patent attorney/agent who drafted the application will likely have to either generate the Sequence Listing herself or attempt to point out each variant referenced in the specification and explain to the one preparing the Sequence Listing exactly how each variant is to be set forth in the Sequence Listing.

As the attorney of record submitting a sequence listing on behalf of my client, it is my responsibility to review the submission. This means that whether or not I prepared the Sequence Listing in XML format myself, I must review the XML file. Whether on my computer screen or printed out on paper, all the requirements and features of the Proposed WIPO ST.26 standard will make it quite difficult and timely to review the XML file. This means additional attorney time and, hence, additional costs to my clients.

I strongly urge that the effective date of the new standard is set to be no sooner than one year following publication of the final rule. I also strongly urge that the effective date is well after 16 March 2013 (i.e. at least six months or more after this date) as us patent practitioners are expected to be quite busy drafting and filing applications prior to 16 March 2013 in order to take advantage of the first-to-invent rules and will therefore have little time for learning and implementing internal firm/practice procedures for converting to any new sequence listing rules.

It is also essential that conversion software that easily and completely converts between the current ST.25 standard and any new standard and software for creating Sequence Listings under the new standard be made available well before the effective date so that applicants, practitioners, and support staff may have sufficient time to learn how to use the software. Such software should be freely available like PatentIn and Checker are now.

As it is currently, compliance with the new standard should not be required for obtaining a filing date. Applicants should still be allowed to submit an application containing biotech sequences in any format and then respond to a subsequent Notice requiring a compliant Sequence Listing by a given date. The shortened statutory due date of such should be extended, at least temporarily, to at least 3 months as it is expected that it may take longer to "convert" a prior Sequence Listing to the new standard.

Continuing applications and other applications containing a sequence listing in the current ST.25 standard, which are relied upon for priority/benefit, should be allowed to proceed under either the current ST.25 standard or the new standard at the discretion of the applicant. A continuing application filed after the effective date, which claims the benefit of or priority to an application having a Sequence Listing filed according to the current ST.25 standard, should benefit from continued availability of a request under 37 CFR 1.821(e).

Last, if a new standard is adopted, I strongly urge that applicants are permitted to provide duplicate sequence data in any format (e.g., in the text of Examples, in Drawings, or as a Sequence Listing under the current ST.25), which may be fully relied upon for support and/or correction of an initial and/or substitute Sequence Listing under the new standard, if needed. In addition, application papers containing such "duplicate" sequence data should not be used for calculating excess page fees or otherwise create additional fees. Thus, I recommend that applicants clearly mark such application papers as "Duplicate Sequence Data".

Thank you for this opportunity to comment on the Proposed WIPO ST.26 standard.

Best
Suzannah
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K.

Sundby,

regards,
Esq.

The views expressed herein are mine and are not to be attributed to any other person or entity including Smith, Gambrell & Russell, LLP or any client of the firm.

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