From: Betsy Haanes
Sent: Monday, July 16, 2012 1:48 PM
To: seq_listing_xml; Wolski, Susan
Cc: Jaume M. Canaves
Subject: Comments on ST.26 Sequence Listing Proposal

Please find attached our comments regarding the Recommendation for the Disclosure of Sequence Listings Using XML (Proposed ST.26), as requested in the Federal Register at 77 Fed. Reg. 28,541 (May 15, 2012).

We appreciate the opportunity to provide feedback. Kindly acknowledge receipt of this email.

Kind regards,

Elizabeth J. Haanes, Ph.D., Reg. No. 42,613

Sterne Kessler Goldstein Fox
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re:

PTO-P-2012-2018

For: **Request for Comments on the Recommendation for the Disclosure of Sequence Listings Using XML (Proposed ST.26)**

77 Fed. Reg. 28,541 (May 15, 2012)

Request for Comments on the Recommendation for the Disclosure of Sequence Listings Using XML (Proposed ST.26), 77 Fed. Reg. 28,541 (May 15, 2012)

Via Internet to: seq_listing_xml@uspto.gov
Susan.Wolski@uspto.gov

The Honorable David J. Kappos
Under Secretary of Commerce for Intellectual Property
and Director of the United States Patent and Trademark Office
Mail Stop Comments – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

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

Dear Under Secretary Kappos:

We wish to provide comments in response to the *Request for Comments on the Recommendation for the Disclosure of Sequence Listings Using XML (Proposed ST.26)*, 77 Fed. Reg. 28,541 (the "Request for Comments") published in the Federal Register on May 15, 2012 (PTO-P-2012-2018).

General Comments

Extensible Mark-up Language (XML) is a well-supported text-based standard for encoding structured data, which is well-suited for exchanging data between client and server systems and which can be used directly by most web browsers. XML is widely used for data exchange among public and commercial sequence databases. Many application programming interfaces (APIs) have been developed for software developers to process

XML data. For example, the output returned by Entrez Programming Utilities (E-utilities), a set of eight server-side programs that provide a stable interface into the Entrez query and database system at the National Center for Biotechnology Information (NCBI), is typically in XML format. Providing biological sequence data in XML format is expected to facilitate sequence indexing and exchange of biological sequence data, improve consistency among databases, reduce the occurrence of parsing errors, and to facilitate sequence searching. Accordingly, we support the establishment of a XML-based standardized electronic format for the submission of biological sequence data to the USPTO and other patent offices.

Rule-Specific Comments

In response to the specific United States Patent and Trademark Office ("USPTO" or "the Office") requests in the above mentioned Request for Comments, we would like to offer the following comments to requests (4) and (6).

Request (4) Definition of a Sequence for which a Sequence Listing is Required

Prohibited sequences: Whereas the current ST.25 standard describes sequences for which a sequence listing is not required, e.g., nucleotide sequence less than 10 amino nucleotides in length, the proposed ST.26 standard prohibits the inclusion of any branched nucleotide sequences or any nucleotide sequences with fewer than ten specifically defined nucleotides. We oppose the proposed ST.26 prohibition.

The stated purpose of the proposed ST.26 standard is "to facilitate searching of the sequence data; and allow sequence data to be exchanged in electronic form and introduced onto computerized databases." See Recommendation for the Disclosure of Sequence Listings Using XML (Proposed ST.26), page 1, paragraph 1. Prohibiting the inclusion of short nucleotide sequences is in direct conflict with this stated goal. Certainly, such a prohibition implies that sequences shorter than ten nucleotides in length will not be included in sequence listings, will not be indexed in computerized databases, and therefore will not be searchable. Furthermore, the proposed ST.26 standard provides no justification for the selection of such length cut-off or reason for the exclusion of "prohibited sequences" from sequence listings.1

We wish to point out that the inventions described in some patent specifications, e.g., oligonucleotide probes or primers used for diagnostics, or pharmacologically active oligonucleotides, may be short nucleotide sequences nine or fewer nucleotides in length. See, e.g., allowed U.S. Patent Application No. 12/245,544, directed to antisense oligonucleotides that are 7, 8, 9 or 10 nucleotide units in length. The inclusion of such sequences in XML sequence listings would provide full disclosure to the public, provide

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1 In contrast, the ST.25 standard provides an explanation as to why certain sequences are not required to be included in sequence listings. "[T]he limit of ten or more nucleotides, while lower than certain industry database limits, was established to encompass those nucleotide sequences to which the smallest probe will bind in a stable manner." MPEP 2422.01 (8th ed. Rev. 8 July 2010).

more complete database sequences, and permit comprehensive database searching of sequence data. Accordingly, we support the removal of the prohibition and, as under the current ST.25 standard, allowing the optional inclusion of nucleotide sequences shorter than ten nucleotides in biological sequence listings.

In accordance with our comments above, we also support the optional inclusion of other categories of sequences deemed "prohibited" under the proposed ST.26 standard, namely amino acid sequences shorter than four specifically defined amino acids and branched nucleotide or amino acid sequences (which would include, e.g., sequences with a heterologous moiety conjugated to an amino acid side chain).

Modified nucleotides: The proposed ST.26 standard specifies that sequences containing any nucleotides that can be represented using any of the symbols set forth in Annex B.1, paragraph 1, Table 1 must be included in a sequence listing. These sequences include, e.g., nucleotides containing modified bases, modified or synthetic sugars, or modified or synthetic 3' to 5' internucleotide linkages. For the same reasons presented above in support of the optional inclusion of "prohibited sequences" in sequence listings, we support the inclusion of sequences containing modified nucleotides that can be represented using any of the symbols in Annex B.1, paragraph 1, Table 1.

Request (6) Transition Issues

We support the development of a software tool that allows processing of biological sequence data in accordance with either the current WIPO ST.25 standard or the proposed WIPO ST.26 standard. We believe that updating and improving the USPTO Patent-In sequence listing generation tool and the USPTO Checker validation tool to generate ST.26-compliant listings and to convert ST.25-compliant listings to ST.26 would facilitate the transition to the new proposed standard. For example, the Patent-In and Checker programs could be integrated into a single interface, and support for platforms other than Windows could be provided. In addition, the source code of the Patent-In and Checker programs could be provided to the public, allowing users to adapt the programs to their specific needs, while still meeting USPTO standards.

Considering the numerous differences between the current ST.25 and the proposed ST.26 standards, we support a 6 to 12 month transitional period to allow for beta testing of Patent-In/Checker software, identify potential platform compatibility issues, and to receive feedback from the public. During this transition period, biological sequence listing could be prepared in accordance with either the current ST.25 standard or the ST.26 standard. We further recommend proactive evaluation of the transition to the ST.26 standard, and the eventual extension of the transition period for another 6 months if excessive implementation errors are encountered.

A key transitional issue concerning the Office application of the proposed ST.26 is the effect of a non-compliant sequence listing, e.g., a sequence listing containing prohibited sequences. The Office is encouraged to provide clarification regarding the effects of filing a non-compliant sequence listing, especially whether lack of compliance may result in failure to secure a filing date.

Along the same lines, another important issue is whether previously-submitted sequence listings in ST.25 can be grandfathered in for use in later-filed continuation or divisional applications. While having a reliable conversion utility as discussed above would be helpful, the safest approach is to use the same sequence listing data for all applications in a family. We would therefore recommend that ST.25 sequence listings that have been previously submitted to the USPTO be accepted without conversion in subsequent continuation and divisional applications.

Conclusion

If you have any questions or would wish further clarification on any of our comments, please do not hesitate to contact us. Thank you very much for considering our view on these important issues.

Respectfully submitted,

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