

AIPLA

American Intellectual Property Law Association

December 21, 2016

The Honorable Michelle Lee
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
United States Patent and Trademark Office
600 Dulany Street
Alexandria, VA 22314

Via email: seq_listing_xml@uspto.gov

RE: Standard ST.26 - Request for Comments on the Recommended Standard for the Presentation of Nucleotide and Amino Acid Sequence Listings Using XML (eXtensible Markup Language) 81 Fed. Reg. 74775 (October 27, 2016)

Dear Under Secretary Lee:

The American Intellectual Property Law Association (AIPLA) is pleased to have this opportunity to present its views on the Recommended Standard for the Presentation of Nucleotide and Amino Acid Sequence Listings Using XML (Proposed ST.26 Standard), published in the Federal Register on October 27, 2016 (81 Fed. Reg. 74775).

AIPLA is a national bar association of approximately 14,000 members who are primarily practitioners engaged in private or corporate practice, in government service, and in the academic community. AIPLA members represent a wide and diverse spectrum of individuals, companies, and institutions involved directly or indirectly in the practice of patent, trademark, copyright, trade secret, and unfair competition law, as well as other fields of law affecting intellectual property. Our members represent both owners and users of intellectual property. Our mission includes helping to establish and maintain fair and effective laws and policies that stimulate and reward invention while balancing the public's interest in healthy competition, reasonable costs, and basic fairness.

AIPLA supports the aspirations underlying the Proposed ST.26 Standard for Sequence Listings. Enhanced accuracy, acceptance by all patent offices, and compatibility with other database providers, if achieved cost-effectively with a relatively smooth transition, would be valuable to AIPLA's members and to our members' clients. AIPLA recognizes and appreciates the incentives and expected benefits of moving to the new standard.

AIPLA appreciates the efforts by the Committee on WIPO Standards (CWS) and the significant improvements made over the prior proposed 2012 XML Standard (77 Fed. Reg. 28541) in view of public comments, including AIPLA's Comment Letter of July 16, 2012. Notably, the Proposed ST.26 Standard does not require every variant of a genus sequence, such as AX₁PLAX₂STHEX₃PLEADER, where X₁ is I, A, F, Y, or is absent; X₂ is I, V, L, or M; and X₃ is I, D, E, N, or Q, provided that X₁, X₂, and X₃ are not all I, to be disclosed in a sequence listing. Instead, the only variants required in the sequence listing are those having (1) their amino acid residues explicitly enumerated in the application, or (2) an inserted or substituted sequence that contains more than 1000 residues.

AIPLA specifically comments on the following items: (a) The Main Body of the Proposed ST.26 Standard and the Guidance Document; (b) Translations, Authoring and Validation Tool; (c) Transition Issues; and (d) Sequence Listing Fees.

(a) Main Body of the Proposed ST.26 Standard and Guidance Document.

AIPLA recognizes the great strides that have been made to make the Proposed ST.26 Standard comprehensive and clear. Nonetheless, because of the complexity of XML language, the discussion of optional sequence information throughout the lengthy Main Body and its Annexes, and then the discussion of required information if optional sequence information is submitted, understanding the minimum requirements for compliance is quite challenging. AIPLA understands that “Annex II - Document Type Definition for Sequence Listing (DTD)” sets forth the minimum requirements for sequence listings. Unfortunately, Annex II is presented in a way that is difficult to understand. Therefore, AIPLA recommends that the Main Body includes, near its beginning, a section itemizing only the minimum requirements for compliance.

AIPLA understands that the words “must”, “should”, and “may” were intentionally used throughout to indicate whether certain information is required in a sequence listing. If, however, the Proposed ST.26 Standard is to be adopted and relied upon, AIPLA suggests the “Definitions” section beginning on page 3, clearly indicate that the use of the word “must” means the indicated information is a requirement, and the use of the word “should” or “may” means the indicated information is not a requirement.

As some parts of the Proposed ST.26 Standard may be interpreted or applied differently, AIPLA recommends that the examples of the Guidance Document are integrated into the Main Body where applicable. This would allow one to readily point to a given example that was followed in order to demonstrate sequence listing compliance.

The proposed features and qualifiers available for annotation of a sequence under the Proposed ST.26 Standard are generally useful. However, it may be burdensome to prepare and adequately review a Sequence Listing in XML format, such that the potential benefits of the Proposed ST.26 Standard may not outweigh its burden.

AIPLA understands that the “feature qualifiers” and “feature keys” used in the Proposed ST.26 Standard are based on the International Nucleotide Sequence Database Collaboration (INSDC) and UniProt specifications in order to facilitate importation of sequences of patent applications into public databases and to facilitate prior art searches of the public databases. The “feature qualifiers” and “feature keys,” however, originated from a non-patent law context and could have unintended consequences as applied to patents. For example, the feature keys used for variants at #93 indicate that the use of “variation” as opposed to “misc_difference” means the indicated residue is a naturally occurring mutation or polymorphism. Similarly, the use of a standard source organism indicates that the given sequence is naturally occurring. AIPLA is concerned that if one mistakenly uses “variation” instead of “misc_difference” or selects a standard source organism, such a mistake will be used against the applicant as an admission that the given sequence is naturally occurring and that such a mistake would be considered a fatal error that may not be corrected.

Certain feature keys, such as “VAR_SEQ” and “VARIANT,” have uses and meanings that (1) a sequence listing preparer might not appreciate, or (2) requires further information not readily

obtainable from the application specification such that the sequence listing preparer must review each mutation, substitution, deletion, and modification of each variant sequence with the applicant or inventor and itemize whether such is a variant produced by alternative splicing, alternative promoter usage, alternative initiation and ribosomal frameshifting, or not. Similarly, a sequence listing preparer might not be able to determine whether a modification to an amino acid residue is a post-translational modification, in order to determine whether the feature key “MOD_RES” is to be used instead of “SITE.”

As previously indicated, AIPLA would also be concerned if WIPO revised the feature keys and qualifiers more frequently than about every 5 years, because of the burdens placed on the U.S. Patent & Trademark Office (USPTO) and on practitioners with respect to rule changes. A significant benefit of the current ST.25 Standard has been the infrequency of changes over the 14 years it has been in effect. The concern is not that the software will have to be updated, but that practitioners and staff may have to adapt too frequently to updates and changes not driven by the patent system.

Thus, AIPLA recommends the development and use of feature keys and qualifiers with indicated uses that are not unduly burdensome and cannot be adversely interpreted, and suggests that the public databases then adopt and implement the feature keys for sequences disclosed in patents rather than the other way around.

(b) Translations, Authoring and Validation Tool.

AIPLA understands that the Proposed ST.26 Standard contains “free text” that will likely be required to be translated upon national phase entry. Because of the complexity and length of the sequence listing in the XML format, it will be challenging for translators and translation companies to identify and extract the “free text” required to be translated. Such challenges will likely result in increased translation fees.

AIPLA understands that the CWS is hoping that the Authoring and Validation Tool will be capable of extracting the “free text” and compiling it into a table that would then be pasted into the specification of an application and translation of such a table would satisfy any translation requirement of the sequence listing “free text.” Unfortunately, this “table” approach will result in extra page fees. Additionally, often applicants are unable to provide a sequence listing at the time an application must be filed. In these circumstances, such a table would not likely be able to be inserted into the specification in view of added/new matter. Thus, the “table” approach will not be of any benefit to many applicants.

Thus, the Proposed ST.26 Standard still presents foreign translation costs as well as extra page fees for such additional information that are significant uncertainties that cause AIPLA concern. Without guarantees that all WIPO member countries will accept the sequence listing produced under the Proposed ST.26 Standard, the new standard may create burden without sufficient off-setting benefit.

AIPLA appreciates that the Authoring and Validation Tool that is intended to be developed will prompt entry of all required data and allow the use of only acceptable values and formats where applicable. In view of the “feature key” and “feature qualifier” issues noted above, AIPLA recommends that the Authoring Tool also clearly sets forth the meaning or use of the applicable feature keys and feature qualifiers that may be selected.

AIPLA also appreciates that the validation function will be available for use by both applicants and International Patent Offices (IPOs). Nevertheless, AIPLA understands that an IPO, such as the USPTO, may use a different validation tool. If the USPTO implements a different validation tool, AIPLA strongly encourages that it be made available to applicants.

AIPLA understands that the Authoring and Validation Tool will be capable of partially converting sequences in current ST.25 Standard (ST.25) to the Proposed ST.26 Standard, but that Proposed ST.26 Standard requires additional information not required by ST.25, which will be required to be manually entered. AIPLA understands that the USPTO does not intend to “grandfather-in” ST.25 sequence listings from parent applications after a given date. AIPLA also understands that it is unknown whether the additional information required by the Proposed ST.26 Standard will be considered statutory new matter under 35 U.S.C. 112. Further, AIPLA is concerned that the inclusion of the additional information required by ST.26 will cause a pre-AIA application to fall under the AIA First-Inventor-to-File provisions. For these reasons, AIPLA strongly recommends that any “feature keys” and “feature qualifiers” are mapped to keys and qualifiers used under ST.25 and that the necessity of any feature keys and feature qualifiers that cannot be mapped be reconsidered.

Additionally, AIPLA urges that the Authoring and Validation Tool be made available at least 6 months, preferably at least 1 year, prior to the transition date so that applicants, practitioners, and support staff may have sufficient time to become familiar with its operation and to develop confidence in their ability to understand the format of the new standard. Such a tool should be available at no cost or at nominal cost.

(c) Transition Issues.

AIPLA sees several significant issues arising from transitioning to the new standard at two distinct circumstances—international application filings and continuing application filings in the US.

International Applications: If the IPOs do not transition to the Proposed ST.26 Standard at the same time, applicants would be required to prepare two separate sequence listings, one under the current standard and one under the Proposed ST.26 Standard, for one international application. Because preparing two separate sequence listings would be burdensome result in increased costs (*e.g.*, preparation and translation fees), AIPLA favors a “Big Bang” implementation as described in the WIPO Circular on the ST.26 transition dated November 18, 2016. Because of the possibility that the additional information required by the Proposed ST.26 Standard may present “added matter,” AIPLA recommends that the transition date be based on the priority date for international applications.

U.S. Utility Applications and Continuing Applications: Similar to the “added matter” concern related to international applications, the additional information required by the Proposed ST.26 Standard may present statutory “new matter” under 35 U.S.C. 112. Thus, AIPLA recommends that the transition date be based on the priority or benefit date for utility applications filed under 35 U.S.C. 111.

AIPLA understands that the USPTO does not intend to “grandfather-in” ST.25 sequence listings into continuing applications after a given transition date. If the additional information required by the Proposed ST.26 Standard is considered statutory new matter, there will be several detrimental consequences:

- One challenging conundrum is a situation in which an applicant must file a sequence listing in the Proposed ST.26 Standard (“new sequence listing”) in a continuing application (“child application”) where the parent application was in the current ST.25 Standard. If the applicant files the new sequence listing on the same day as the application papers for the child application, the statutory new matter presented by the Proposed ST.26 Standard could cause the child application and any subsequent applications to lose not only its status as a First-To-Invent application, but also the rightful benefits of pre-AIA laws.
- Alternatively, if the applicant files the new sequence listing after the filing date of the child application, the statutory new matter presented by the Proposed ST.26 Standard could prevent an amendment entering the new sequence listing into the child application.
- Even more problematic would be the situation where the USPTO enters the amendment entering the new sequence listing and grants the patent, as a court could then find the claims having limitations to SEQ ID NOs to include additional limitations (*i.e.*, the additional information required by the Proposed ST.26 Standard) that are not supported by the original application papers, and/or not entitled to the priority or benefit date of the parent application, and thereby find the claims invalid.

Thus, enacting a rule under which applicants are required to submit a sequence listing complying with the Proposed ST.26 Standard in continuing applications where the sequence listing in the parent application was submitted under the current ST.25 Standard has potential detrimental consequences. AIPLA urges the USPTO to consider whether it can use its rule-making authority to avoid any possibility that the additional information required by the Proposed ST.26 Standard could be interpreted as statutory new matter. If, however, the USPTO cannot use its rule-making authority to prevent such detrimental consequences, AIPLA respectfully suggests that the USPTO may not have the authority to implement the Proposed ST.26 Standard in a way that would result in a substantive legal impact with detrimental consequences. Should the USPTO determine that it cannot promulgate additional regulations to address the potential detrimental consequences, including the possibility of statutory new matter, AIPLA strongly encourages the USPTO to permit grandfathering of ST.25 sequence listings of parent applications into continuing applications.

Transition Date: For both international applications and U.S. utility applications, a transition date of July 1, 2019, is acceptable. The transition date, however, should be set no sooner than one year following publication of a final rule. However, compliance with the new standard should not be required for obtaining a filing date. Specifically, applicants should be allowed to submit an application containing nucleotide and/or amino acid sequence disclosures in any format, with an Official Communication requesting submission of a Sequence Listing complying with the new standard to be issued thereafter as part of pre-examination processing.

Applicants’ Option: Because of the possibility that the additional information required by the Proposed ST.26 Standard may present “added matter” or “new matter”, both international and U.S. applications claiming priority to or the benefit of a prior application having a sequence listing in the current ST.25 Standard, which are relied upon for priority/benefit, should be allowed to proceed

under the current ST.25 Standard or the new standard at an applicant's discretion. A continuing application filed after the transition date, which claims 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).

AIPLA also urges that applicants be permitted to additionally include 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. Given the critical nature of sequence data to the claimed invention of many biotechnology applications, and the potential for error when generating a Sequence Listing, most practitioners currently include such "duplicative" sequences. Application pages that only set forth sequence data should not be counted in a calculation to assess application size fees, or otherwise create additional fees. Essentially, AIPLA favors the third option discussed in paragraphs 21 to 24 of the WIPO Circular.

(d) Sequence Listing Fees.

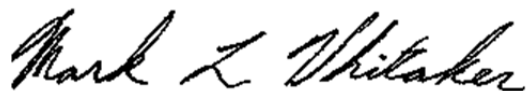
On October 3, 2016, the USPTO proposed new fees for handling mega-sequence listings and a late furnishing fee for providing a sequence listing in international applications.

The stated reasons for the mega-sequence listing are the costs associated with extra data storage requirements and requisite special handling. AIPLA acknowledges that the XML format will likely result in sequence listing file sizes to increase at least 3 times, and likely about 4-5 times. The XML format, however, is expected to streamline and automate some of the handling of sequence listings. Thus, AIPLA encourages that the mega-sequence listing fees, if implemented, be reconsidered.

AIPLA also urges that the late furnishing fees, if implemented, be waived for a given period after the implementation date, as it is expected that many applicants will likely find it challenging to timely submit a sequence listing in compliance with the new standard until they gain more experience with the new standard and Authoring and Validation Tool.

AIPLA acknowledges the effort by the USPTO and CWS to update the international standard for sequence listings. These comments have been provided in the spirit of making proposed changes in a way that is compatible with the needs of our members. Thank you for allowing AIPLA the opportunity to provide comments on the Proposed ST.26 Standard for sequence listings.

Sincerely,



Mark L. Whitaker
President
American Intellectual Property Law Association