

## WIPO ST.26:

### A Roadmap To The Future of Sequence Listing Compliance

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A new Sequence Listing Compliance Standard (“ST.26”) was conceptualized over seven years ago. Since 2010, there have been many questions, comments, concerns, and suggestions regarding how the current Standard (“ST.25”) will change, the resources that will be provided by the patent offices to accommodate these changes, and the timeline for implementing the new standard. So, when will ST.26 go into effect? To answer that question, let's look back at why and when this all began, as well as where we are headed!

In **September 2010**, the European Patent Office (“EPO”) requested that discussions for a new Sequence Listing standard should be commenced at the Committee of WIPO Standards' (“CWS”) first session to take place in October 2010. Most notably, the EPO requested that the new standard should consider changing the required worldwide Sequence Listing format from ASCII text to eXtensible Markup Language (“XML”).

As the current standard for Sequence Listing compliance was established in 1998, and no subsequent updates have been introduced since [despite significant advancement in science and biotechnology patent application disclosures], it was the EPO's belief that current ST.25 was no longer sufficient to accurately describe biological sequences. In addition, the EPO made it a goal for the new standard to be "filing-route neutral" so as to have the same requirements in all national, regional, and international offices.

In **October 2010**, based on the EPO's request, a Task Force consisting of 13 intellectual property offices, as well as the International Bureau, was created by the CWS at the first session to deal with Task 44 - "Prepare a recommendation on the presentation of nucleotide and amino acid sequence listings based on eXtensible Markup Language (XML) for adoption as a WIPO standard" (document CWS/1/5)." The EPO pledged that

the new standard would provide both universality and flexibility for worldwide Sequence Listing compliance.

Additionally, in cooperation with the European Bioinformatics Institute (“EMBL-EBI”), the EPO developed a new software program to assist with the preparation of XML formatted Sequence Listings. Titled "Biological Sequence Submission Application for Patents (“BiSSAP”)", the software includes options for generating ASCII and XML formatted Sequence Listings, as well as a validation process for both types of submissions. Once finalized, BiSSAP would be freely downloadable from the EPO's website for applicants use in Sequence Listing compliance, while the U.S. Patent and Trademark Office (“USPTO”) indicated that it would develop a similar software replacement for PatentIn should the standard be adopted.

From **February 2011** to **March 2012**, the Task Force worked on the development of the standard through multiple discussions on their internal wiki and finalized the draft standard in March 2012. The draft included the “Recommendation for the disclosure of sequence listings using XML (Proposed ST.26),” “Annex B.1. Controlled vocabularies” and the “Document Type Definition (DTD for Proposed ST.26)”, the latter of which included the specific XML language required under the new standard. As the documents were agreed upon, the Task Force members reached out to the public for their review and comments on the standard.

In **May 2012** the USPTO published in the Federal Register, Vol. 77, No. 94 a “Request for Comments on the Recommendation for the Disclosure of Sequence Listings Using XML (Proposed ST.26).” The office asked that comments be submitted by mid-July 2012 and indicated that they would be made available for the public to review. In the same vein, various other patent offices, including the EPO, also requested submission of public comments.

By the end of **August 2012** the USPTO and EPO had received, reviewed and published the comments submitted to their respective offices. Comments were submitted from a variety of sources, including individuals, law firms, database providers, biotech companies, etc. The comments brought to light some significant issues pertaining to the

new XML format, such as the larger file size, and the difficulty of manually reviewing XML formatted files. Public comments also expressed that the new standard would add additional time and cost to applicants, but perhaps the most impacting concern mentioned in the comments was the need for a conversion software solution and clear expectations for the transitional period from ST.25 and ST.26.

From **August 2012** to **September 2013**, the Task Force resumed discussion of the standard taking into account the issues raised by the public comments. In addition, the Task Force consulted with database providers for their input on the format of the new Sequence Listing standard to ensure data exchange would be efficient. In September, the sixth round of discussions was completed and the draft standard was ready for final review and acceptance.

In **January 2014** the draft was placed in WIPO's wiki for review by Task Force members with the hope of approval. It was the desire of the Task Force to have the draft standard accepted for adoption at the fourth session of the CWS to be held in May 2014.

At the fourth session of the CWS held in Geneva, Switzerland (**May 2014**), the Task Force was able to agree to adopt the standard (as anticipated), but since the meeting agenda was not formally adopted, the decision could not be finalized.

Further, it was decided by the Task Force at the informal fourth session that the patent offices should delay the implementation of the standard until a decision had been made regarding the transition from ST.25 to ST.26. The Task Force would continue to consider the transitional aspect of ST.26 and would have its recommendations on the subject ready for discussion at a future session. Possible options for the transition included (1) the acceptance of both ST.25 and ST.26 compliant listings by patent offices for a certain amount of time, or (2) a hard cutoff date after which all ST.25 Sequence Listings would be rejected and all listings would need to be ST.26 compliant.

At the reconvened fourth session of the CWS (**March 2016**) the standard entitled "Recommended standard for the presentation of nucleotide and amino acid sequence listings using XML (eXtensible Markup Language)" was formally adopted. The CWS

also approved the addition of an Editorial Note to be included in the new standard stating "[the CWS] agreed to ask industrial property offices to postpone the preparations for implementation of this new WIPO Standard ST.26 until the recommendations for the transition from WIPO Standard ST.25 to the new Standard ST.26 is agreed on by the CWS at its next session." The Task Force will conduct an eighth round of discussion to complete a technical assessment on the transition which will be submitted for possible approval at the fifth session of the CWS (**May-June 2017**). It is only after the transitional aspects of this initiative have been finalized that patent offices may begin working on the development of their IT systems to address the new requirements.

While discussions on the transition are ongoing, in **October 2016** the USPTO published a notice in the Federal Register at 81 FR 74775 titled "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)." The Office asked that comments be submitted by **December 2016** and for comments pertaining to (1) the main body of the standard, (2) the guidance document and (3) an authoring and validation tool. Based on the comments published, one of the largest concerns is the increase in the resources required to prepare a Sequence Listing (whether it be the increasingly large file sizes or the increase in the amount of time required to prepare a Sequence Listing), as well as the usability of the authoring tool and timeline for implementation.

Over seven years after the initial task force was created, there are still many questions. While the initiative to transition worldwide Sequence Listing compliance to ST.26 has certainly seen progress, it may be years until implementation occurs. Not knowing when ST.26 will take effect, the type of corresponding preparation/validation software to use, or the training provided, begs the question: "How will you prepare?"

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