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QUESTIONS: SEQUENCE LISTING RULES ST26

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1. For the ST.25, listings were in ASCI.txt and easy to download and review. Now that listings will be in XML, how do we read listings and compare sequences with other sequences e.g. in the art? "Other " may be in 25 or 26 format.

Answer: XML is more difficult to read, but not impossible. The WIPO Sequence tool has functionality to render the XML file to a human readable format. For comparing the sequences themselves, cut and paste into a sequence comparison tool. WIPO plans to incorporate a sequence listing reader into PATENTSCOPE database for published patent applications that will allow viewing XML listings in human-readable format.

2. For applications with listings filed in ST.25 but for which CON or DIV will be filed after July 1, which format do we use?

Answer: The actual filing date is what determines whether ST.25 or ST.26 is required. The Federal Register notice for US practice articulates this in section found at 87 Fed. Reg. 30810. The WIPO FAQ 29 articulates this same requirement. That is, if the actual filing date is on or after July 1, 2022, a Sequence Listing in XML format will be required EVEN IF an earlier filed application to which a benefit or priority claim is made contained a ST.25 formatted Sequence Listing.

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3. Do you recommend filing CON or DIVs in US or non-US countries, before July 1?

Answer: Not really something USPTO can answer or can advocate for. This is something that AIPLA or a practitioner familiar with the requirements should address. Keep in mind that further CONS/DIVS filed in the US after 7/1/2022 will require transforming the ST.25 Sequence Listing to ST.26 Sequence Listing. Filing before July 1, would only delay the compliance with submitting a Sequence Listing in XML file format until a second or third CON/DIV is filed in the US.

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4. Do you recommend converting sequence listings for pending applications in ST.25 to ST.26? Would that be “new matter”?

Answer: The application filing date controls. If the relevant filing date is before July 1, an application CANNOT use ST.26. It must must continue in ST.25. Because the concern about new matter was discussed during drafting of the standard, Annex VII provides guidance on how to ensure transformation of a ST.25 Sequence Listing to a ST.26 Sequence Listing in XML format without new matter being introduced.

5. Because now D-amino acids, linear portions of branched sequences, nucleotide analogs, and structures are required, does that affect your answer for questions 2-5 above?

Answer: If D-amino acids, linear portions of branched sequences, nucleotide analogs, and structures are disclosed in the specification of an application filed before July 1, 2022 and an application filed on or after 7/1/2022 claims the benefit or priority to such earlier filed application then these sequences would be required to be included in a Sequence Listing XML that complies with 1.831-1.835. Support for adding those sequences would be found in the specification that disclosed those sequences and including in a the Sequence Listing XML which includes the D-amino acids, linear portions of branched sequences, nucleotide analogs, and structures would not be new matter.

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6. The new Rules say that all applications with a filing date or international filing date before July 1, 2022 must file Sequence Listings under ST.25 rules:

What counts as the “filing date” for different applications (provisional, non-provisional, continuation, national stage, PCT)

Answer: The “filing date” is the actual filing date of the application, it would be the date that the requirements for being entitled to a filing date are met as discussed in MPEP 506. For national phase applications, the filing date is the PCT filing date. For PCT, it would be the international filing date (when PCT Article 11 requirements are met)

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7. After July 1, 2022, can an application claiming benefit to an earlier application still rely on the Sequence Listing from the parent, in ST.25 format?

Answer: A ST.26 compliant Sequence Listing in XML file format will be required in applications filed on or after 7/1/2022 regardless of any benefit or priority claims to earlier filed applications where a ST.25 Sequence Listing in ASCII file format was filed. If the question is asking about written description support for the ST.26 Sequence Listing based on the ST.25 submission, then USPTO would agree that the earlier submitted Sequence Listing provides support for the later ST.26 compliant Sequence Listing.

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8. If the ST.25 sequence listing contained SEQ ID Nos for sequences with fewer than 4 specifically defined amino acids or fewer than 10 specifically defined nucleotides, must they be removed in the ST.26 sequence listing if one is later needed? Must the SEQ ID Nos of the resulting set be re-numbered?

Answer: Sequences with fewer than 4 specifically defined amino acids or fewer than 10 specifically defined nucleotides cannot be included in an ST.26 sequence listing. For conversion of an ST.25 containing these types of sequences – these can be treated as "skipped sequences" in the ST.26 sequence listing, so there will be no need to renumber subsequent sequences.

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9. Can we submit the new sequence listing via EFS-Web?

Answer: A Sequence Listing in XML file format can ONLY be submitted electronically through Patent Center (up to 100 MB) or on physical media (above 100MB).

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10. Do you know to what extent non-PCT countries are going to accept ST26 sequence listings?

Answer: We do not know which non-PCT countries will implement ST.26. Applicants will need to contact any individual non-PCT countries to ask. However, the global implementation of ST.26 on July 1, 2022 was a decision adopted by the WIPO General Assembly, so we expect WIPO Member States to follow the decision. In case of a concern with a particular WIPO Member State, please let WIPO know and we can contact the concerned Office.

11. If some countries require ST25 and other countries require ST26, how is one supposed to reconcile SEQ ID Nos in international applications to meet both standards when they have different requirements as to what needs a SEQ ID NO. and what doesn't? Different specs?

Answer: All PCT member countries have agreed to implement ST.26 for disclosures of nucleotides and/or amino acid sequences in patent applications. As to other non-PCT countries, this will be a country by country determination and USPTO can only speak to what USPTO will require.