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Webinar: WIPO ST.26 Introduction

hosted by the International Bureau of WIPO

Virtual, April 21, 2021
12:00 – 13:30 (CEST)

RESPONSES TO QUESTIONS

prepared by the International Bureau of WIPO

Following are the responses to the questions raised at the Webinar.

Q1: If the application is filed before January 1, 2022, but without a sequence listing. In which format should the sequence listing be filed as late-filed document if requested after 1st January 2022?

A1: This is a decision for the Office, according to their own national law and practice. If an application is filed without a sequence listing in the correct format, under the PCT a receiving Office can request a sequence listing under Rule 13ter. However, as the filing date is prior to January 1, 2022 this should be filed in WIPO ST.25 format. This is the recommendation for national law equivalents also, but you should check any particular national implementation where this may be relevant to you to be certain.

Q2: If I file a PCT application on January 1, 2020 with an ST.25 SEQ listing, and then during regional phase (e.g. at the EPO) file a divisional on/after January 1, 2022, will I have to use ST.26 on the divisional, or can I use the original ST.25 SEQ listing?

A2: This is a matter of national law. However, the recommendation, following extensive discussion among national Offices of the desire to switch to ST.26 as quickly as possible, is that since the filing date of the child application is after the big-bang date of January 1, 2022 the sequence listing for the child application should be compliant with WIPO ST.26.

Q3: If I have used ST.25 in the priority application, do I need to convert that to ST.26 if the PCT filing date is after January 1, 2022?

A3: Yes, you will need to convert the sequence listing to ST.26 for use as part of the description in the later PCT application filed on/after 1 January 2022 – and make any modifications that are necessary according to development of the patent application in the meantime. However, there is no need to convert the sequence listing in the priority document as such. That should remain in the ST.25 format in which it was originally filed

Q4: Why is there a minimum length requirement of 4 amino acids? For instance the 4 AA lower limit is not optimal for antibody CDR sequences, which can be as small as 3 AA.

A4: The minimum length requirements in ST.26 was recommended in order to ensure that sequence listing databases are not cluttered with very short sequences which may make searching difficult.

Q5: What are the plans, if any, to convert into ST.26 prior filed sequences listings which are not compliant with ST.25?

A5: We do not currently have any plans to convert ST.25 sequence listings to the new ST.26 format, nor are we aware of any other patent Offices who plan to do so. Also, we note that there are variants of ST.25 format being used by applicants and Offices. This is one of the reasons behind the development ST.26. The ST.25 import functionality of WIPO Sequence is developed assuming the imported ST.25 file is compliant with WIPO Standard ST.25 as defined. Therefore, if the imported "ST.25" sequence listing is not compliant with ST.25, the process of importation and the quality of transformed sequence listing to ST.26 using WIPO Sequence is not guaranteed.

Q6: According to WIPO ST.26 "only the earliest priority application can be included" but different sequences within a sequence listing may have different earliest priority applications. For example, SEQ ID NO 1 may be first disclosed in a January 1, 2022 application and SEQ ID NO 2 may first be disclosed in a February 1, 2022 application. Which priority application should be included? In other words, should the earliest

priority application for any disclosed sequence be included or the earliest priority application for all disclosed sequences?

A6: The earliest priority application for the any of the sequences listed in the sequence listing should form part of the ST.26 sequence listing. In addition, all bibliographic data included as part of the general information part of an ST.26 sequence listing, including the definition of the earliest priority application, is mainly to associate it with the relevant patent application.

Q7: Must applicants provide an annotation to explain why they chose synthetic construct or unidentified for the organism, like in ST.25?

A7: In WIPO ST.26, there is no need to annotate why a particular organism is identified as synthetic construct or unidentified ('unknown' is only used in ST.25). However, a note feature MAY be added (see paragraph 83 of WIPO ST.26) to provide additional details for any human-made organisms which should be identified as a 'synthetic construct'. A note feature SHOULD be added (see paragraph 81 of WIPO ST.26) to provide any known taxonomic information known for any naturally occurring organisms labelled with organism 'unidentified'

Q8: If a divisional application is filed in 2022, which claims priority from an application filed in 2021, which Standard should it comply with?

A8: If a sequence listing is required for any application filed after January 1, 2022 then it should be compliant with ST.26.

Q9: What happens when you cut/paste an RNA sequence that lists "u"? Will the software replace the "u" automatically or are we required to amend the listing by hand?

A9: WIPO Sequence will automatically, on import of an ST.25 sequence listing, convert all of the 'u' symbols to 't' symbols for an RNA sequence.

Q10: In renewal of registration, what should be done if the original application was filed before January 1, 2022? Do we need to follow the format you are telling us now?

A10: We are not clear exactly what the question means. The PCT has no "renewal of registration" procedure and as far as we are aware, no national law requires submission of a sequence listing as part of the procedures for renewal of a patent or of a patent application. If you would like to resend the question with more context to help us identify the relevant procedure more clearly, we would be happy to try to respond.

Q11: I use PatentIn 3.5 for generating sequence listing. Do I need to reinstall the software to generate ST.26 format sequence listings?

A11: PatentIn is a software tool used to generate ST.25 sequence listings and we are not aware of any plans to update it to generate ST.26 sequence compliant listings. Instead, the International Bureau in collaboration with Offices has developed a common desktop tool for this purpose which can be downloaded from the following website:
https://www.wipo.int/standards/en/sequence

Q12: What is the INSC database mentioned during the answer by the United States Patent and Trademark Office?

A12: A background on the INSDC databases was provided during the presentation (slide 4). Please refer to the published slide deck at:
https://www.wipo.int/edocs/mdocs/mdocs/en/wipo_webinar_standards_2021_1/wipo_webinar_standards_2021_1_www_536511.pdf

More information can be found at: http://www.insdc.org/

Q13: WIPO previously stated that there would be sample ST.26 test data available sometime around mid-year 2021. Do you have any more specific dates for this test data?

A13: Test data is provided for applicants on a demand basis. However, we would recommend instead that your download WIPO Sequence and import an ST.25 sequence listing and convert it to an ST.26 sequence listing using the guidance provided in Annex VII of WIPO ST.26. This will allow you to generate unlimited ST.26 test sequences and also help familiarize yourself with the tool.

Q14: Are you going to send the copy of slides to the participants later?

A14: The slide deck presented during the webinar is already published on the same WIPO webinar event page that the registration link was available on at: https://www.wipo.int/meetings/en/details.jsp?meeting_id=62848

You should also have received an email with this link after the sessions as a registered participant.

Q15: Will the PatentIn be updated to ST.26 standards or must we use the WIPO Sequence tool?

A15: As far as we were informed, PatentIn will not be updated to generate ST.26 sequence listings and its use will be phased out once ST.25 is no longer the valid format.

We recommend you to contact the USPTO for further details on their plans to update this tool. WIPO Sequence tool has been developed in close collaboration with Offices, including the USPTO in order to ensure that the tool supports applicants appropriately to prepare ST.26 compliant sequence listings. Even though applicants have the freedom to use other tools to generate a sequence listing compliant with ST.26, we encourage applicants to use WIPO Sequence, a software tool dedicated to the authoring and generating of ST.26-compliant sequence listings.

Q16: Will a sequence listing filed after 2022 be published in the XML format you showed?

A16: While it is up to IP Offices to determine how they publish their patent applications (including the sequence listing which forms part of the description), it is recommended that the sequence listings are published in the same format that they are received in.

Q17: Why is the information in the final product of an XML so hard to read? When looking a one sequence it seems ok but as we know sequences can be quite long and would seem overwhelming to review.

A17: Looking at an XML document for the first time can be overwhelming but the information provided here, once you are familiar with elements and attributes, should be clearer with components tagged with relevant descriptive information. For ST.25 it was necessary to remember what each of the numeric identifiers represented.

The WIPO Sequence desktop tool can also produce the sequence listing, once validated in one of two "human-readable formats": HTML and Text-based. In both of these formats, the XML tags are stripped from the document and formatting has been added.

However, once an ST.26 sequence listing is generated with a tool such as WIPO Sequence, as it has passed the validation check it is not necessary for the user of the tool to read through the entire sequence listing to check it.

Q18: During the presentation, it was indicated that sequence listings can also be generated using an XML editor. This might lead to errors. Do the offices check and correct (or ask for corrections) so the content is always in line with the requirements?

A18: There are two main components to the WIPO Sequence tool suite: the WIPO Sequence desktop tool and the WIPO Sequence Validator. The second component is a web service developed for Offices to check that the sequences filed with them are compliant with WIPO ST.26. It is only necessary for offices to read the verification report generated after validation and not the sequence listing itself.

Additionally, it is not recommended for Offices to correct sequence listings. If there are problems that should be addressed, then this should be undertaken by the applicant.

Q19: Where is the data contained within the Persons and Organizations custom list stored? Does WIPO manage a harmonized database of applicants/inventors?

A19: The applicants and inventors, saved using their local instance of the WIPO Sequence desktop tool, are only saved locally and accessible using the persons/organizations tab. There is no harmonized database of applicants/inventors that the International Bureau manages.

Q20: Can an Office use the WIPO Sequence desktop tool to validate a sequence listing rather than incorporate the WIPO Sequence Validator service into their internal IT environment?

A20: While the validation performed by the WIPO Sequence desktop tool and the WIPO Sequence Validator are very similar, they are not 100% the same (see question 3 of the FAQ). It is recommended that the Offices use WIPO Sequence Validator, which is the web service designed to perform the full validation of a filed sequence listing to ensure it complies with WIPO ST.26.

Another advantage of using WIPO Sequence Validator is that it is possible to batch process the filed sequence listings rather than having to upload them one-by-one to the desktop tool.

Q21: Why does WIPO ST.26 only support the inclusion of only one inventor? What about the other listed inventors if there is more than one?

A21: For an ST.26 sequence listing, it is only mandatory to provide one applicant and optionally one inventor. In WIPO Sequence, it is possible to import/create all of the relevant applicants and inventors and select one which will appear in the general information part of the generated sequence listing. As explained above, all data defined in the general information part is mainly to link the sequence list to the associated patent application.

Q22: A major concern for us is the preparation of larger sequence listings (e.g., for 100, 500, 1,000, 10,000 sequences). Is this being taken into consideration with respect to software performance?

A22: Yes, we took it into account when WIPO Standard ST.26 was developed and consequently the development project of WIPO Sequence tool was launched. It is noted that the validation of an ST.26 sequence listing takes longer than a corresponding ST.25 sequence listing because of both the size of XML format and the more comprehensive validation procedure based on

Standard ST.26. Both compliance with the DTD and the verification rules derived from the Standard must be checked.

The WIPO Development team has heard the performance issue with large sequence listing file during the testing by some registered end users and we are exploring to improve the performance of the tool.

Q23: What is the maximum number of sequences tested when importing and validating sequence listings?

A23: According to our internal testing, currently the tool does not perform well beyond 200k size sequence file (~250 Mb). Even though the validation process is not fast with a large size file, the tool shows the progress of the import or validation process so users are aware that the tool continues to process the sequence listing and has not crashed.

Q24: Will there be workshops on using WIPO sequence?

A24: Yes, there was a webinar held on WIPO Sequence on Wednesday, April 28.
The recoding of this session is available at:
https://www.wipo.int/meetings/en/details.jsp?meeting_id=62849

Q25: I downloaded WIPO Sequence to test it. My sequence listing can be validated without errors, with a few warnings provided. The problem I encountered is when I click the button to generate sequence listing, the software does not generate it. What could be the potential problem?

A25: It is difficult to determine the exact problem without looking first at your verification report after validating your ST.26 project. There are two classes of messages returned within this report: errors and warnings. Errors must be addressed before you can proceed but a sequence listing can be generated ignoring the warnings. However, these warning messages are provided for the attention of the author of the sequence listing as something that should be addressed.

Q26: If a sequence is submitted by using a WIPO Sequence tool then surely there is no need to validate that same sequence listing by patent Offices, as it will already be compliant with ST.26?

A26: According to prior discussions with patent offices, all Offices will likely check the sequence listing regardless whether the sequence listing was generated by WIPO Sequence. It is up to the Offices to decide whether or not they need to check it again. For most cases, if WIPO Sequence tool was used to generate the sequence listing, it is expected that the validation result from WIPO Sequence (by applicants) and WIPO Sequence Validator (by Offices) should be the same.

However, there are some verification messages that have a different severity (error versus warning) within WIPO Sequence verification report compared to the report generated by the WIPO Sequence Validator service. This is due to the fact that the Validator service was written to meet the specific requirements of an Office.

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