UNITED STATES PATENT AND TRADEMARK OFFICE



Common sequence listing compliance errors

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Topics

- ST.26 sequence standard transition errors
- Errors common to ST.25 & ST.26



Reasons compliance is critical

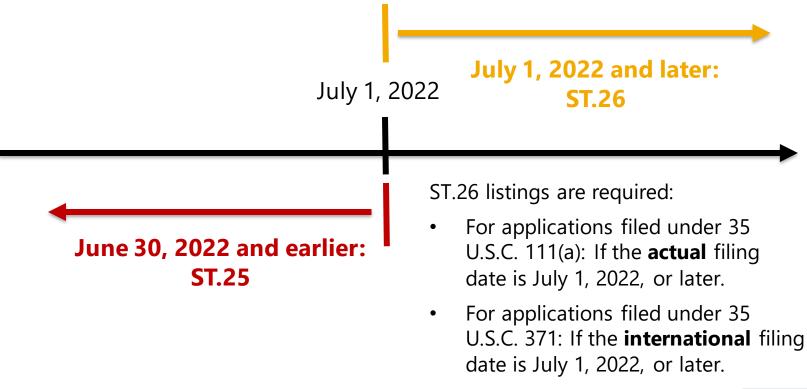
- Necessary for sequence searches
- Incomplete disclosure
- Potential new matter
- Delays in prosecution and/or issuance
- Withdrawal from issue
- Incomplete sequence databases

Sequence compliance: CFR §§ 1.821-839 and MPEP §§ 2412-35.



ST.26 transition errors

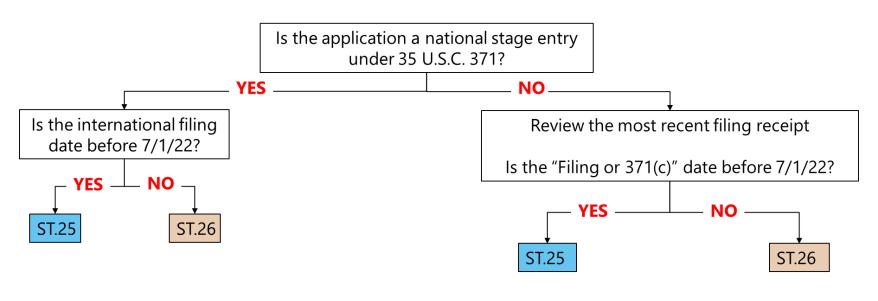
Transition to ST.26





Transition to ST.26 (cont.)

Decision tree for determining appropriate sequence format in applications filed after July 1, 2022





Electronic filing

- **Issue applicants observe:** the USPTO Patent Electronic System (PES) will not permit a sequencelisting.TXT file for applications filed on/after July 1, 2022.
- This does **DO NOT** mean you should circumvent the PES and upload a sequence listing in ASCII file format as something else, like a table or chemical drawing, when an xml is **REQUIRED**.



Skipped sequences

- Applicants occasionally supply sequences in SEQ.XML that were permitted in ST.25 but are prohibited in ST.26.
 - Example: parent case (under ST.25) listed sequences with <10 nucleotides or <4 amino acids → child case uses same sequence listing (under ST.26).
- SEQ ID NOs containing prohibited sequence types will appear in the sequence listing but will not have any sequence data.
- Examiners will object to the specification until any reference to the relevant SEQ ID NO: is removed from the specification.
- To avoid objections and/or further prosecution delays, applicants should file a sequence listing and specification that comply with ST.26.
 - Example: amend specification to remove "SEQ ID NO:" references to prohibited sequences.

ST.25 (<4 amino acids optional)

```
<210> 9
<211> 3
<212> PRT
<213> Artificial Sequence
<220>
<223> Epitope

<400> 9
His Gln Leu
1
```

ST.26 (<4 amino acids prohibited)

```
SEQ ID NO: 9 moltype = length = undefined
```



Errors common to ST.25 & ST.26

The "Top 10" error list

- Required "SEQ ID NO:" label missing in specification and/or drawings.
- No CRF (computer readable file) (i.e. "ASCII" for ST.25, "XML" for ST.26) filed.
- CRF rejected and not supplemented with new file.
- CRF does not include all of the covered sequences in the disclosure.
- Amended sequence listing filed without required new matter statement.
- Incorporation by reference statement missing or contains wrong information.
- Not including complete substitute specification when required.
- Sequence listing included in specification.
- Sequences merely duplicated in drawings.
- Non-contiguous segments of a larger sequence or segments from different sequences not presented as a single sequence with a single sequence identifier.



Applicant resources

 Science and Technology Information Center (STIC) Sequence Systems Service Center 571-272-2510

SequenceHelpDesk@uspto.gov

 Patent Cooperation Treat (PCT) Help Desk (for 371 applications)

571-272-4300



Questions?



