

**UNITED STATES
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Standard ST.26: Common Mistakes and Best Practices

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UNITED STATES
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To send in questions or comments during the webinar, please email:

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Agenda

- Compliance with US rules
- Electronic filing
- WIPO Sequence authoring tool
- Compliance with ST.26 requirements
- ST.26 sequence listings in PCT and national phase applications

Compliance with US rules

Compliance with US Rules

Filing date, filing date, filing date. . .

- Application filing date controls what format of sequence listing is required. Applications filed before July 1, 2022, must comply with ST.25 (37 CFR 1.821-1.825). Applications filed on or after July 1, 2022, must comply with ST.26 (37 CFR 1.831-1.835).
- See Federal Register notice 87 Fed. Reg. 30806, 30806: "*Applicability date*: Patent applications filed on or after July 1, 2022, having disclosures of nucleotide and/or amino acid sequences as defined in 37 CFR 1.831(b) must comply with new rules for submission of a "Sequence Listing XML" in accordance with 37 CFR 1.831 through 1.835."
- See Federal Register notice 87 Fed. Reg. 30806, 30807: "Applications pending prior to July 1, 2022, will not have to comply with WIPO Standard ST.26; rather, such applications will require the submission of a "Sequence Listing," as defined in 37 CFR 1.821(a), in compliance with 37 CFR 1.821-[sic]1.825."

Compliance with US Rules

What we have seen:

- Applicant receives pre-examination notice regarding sequence compliance on July 11, 2022 for an application filed June 27, 2022.
- Applicant erroneously submits a sequence listing in xml file format.
- Applicant receives a notice of incomplete response to the original notice, time period continues to run from the original notice.

Compliance with US Rules

Sequence compliance in applications with benefit and/or priority claims to prior filed applications:

- As previously stated, it is all about the actual filing date of the application.
- Whether the present application has a benefit or priority claim under 35 USC 119, 120, 121 or 365 to a prior filed application, if the actual filing date is on or after July 1, 2022, the benefit or priority claim is of no consequence. A sequence listing in XML file format in compliance with ST.26 (37 CFR 1.831-1.835) is **REQUIRED** for applications filed on or after July 1, 2022 having nucleotide and/or amino acid sequence disclosures that meet the definition of 1.831(b).

Electronic filing

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**.

Electronic filing

- **Issue applicants observe:** EFS-Web won't let me file an XML.
- This does **DO NOT** mean that you should change the file extension from .xml to .TXT to file in EFS-Web.

Electronic filing

- **Issue applicants present:** Using characters such as { or / in a "Sequence Listing XML" file name.
- 37 CFR 1.834(a)(3) specifically states:

"(3) Be named as *.xml, where "*" is one character or a combination of characters limited to upper- or lowercase letters, numbers, hyphens, and underscores, and the name does not exceed 60 characters in total, excluding the extension. No spaces or other types of characters are permitted in the file name."

Electronic filing

- **Issue applicants observe:** I don't like using Patent Center so I will file the majority of my application in EFS-Web and file my "Sequence Listing XML" as a follow-on paper in Patent Center.
- Patent Center is not **JUST** for docx submissions. Make sure that if you are doing a hybrid filing (part in EFS-Web and part in Patent Center) that you allow sufficient time to generate a acknowledgement receipt to have information to file the XML in Patent Center as a follow on document.

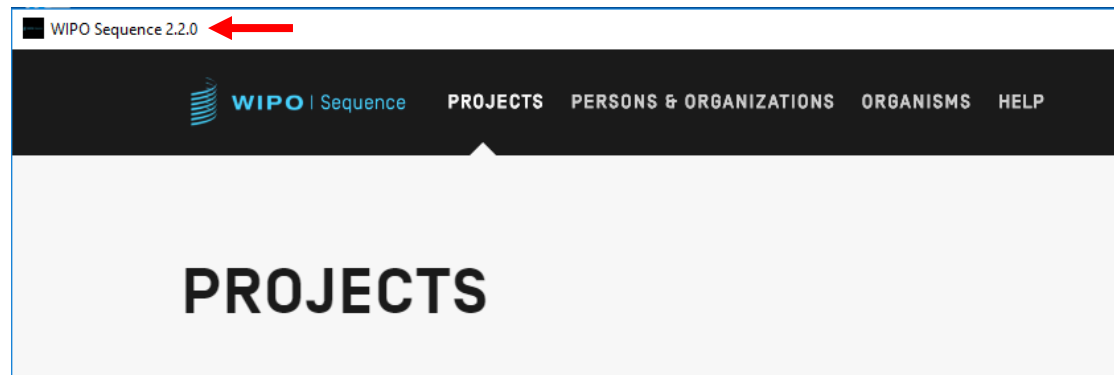
Questions?



WIPO sequence authoring tool

WIPO sequence authoring tool

- Always ensure you are using the most up-to-date version of WIPO Sequence.
- Out of date versions of WIPO Sequence may generate a non-compliant sequence listing and/or have bugs.
- The version number is displayed in the upper left hand corner of the interface.



WIPO sequence authoring tool

- You can get the latest version of WIPO Sequence by allowing the software to auto-update if you have an internet connection.
- Alternatively, you can download WIPO Sequence here:

<https://www.wipo.int/standards/en/sequence/index.html>.

For Applicants

WIPO Sequence

A standalone desktop application available for Windows, Linux and MacOS. A [User Manual PDF](#) is provided to assist applicants in generating their compliant sequence listings.

Need help?

Visit the Knowledge Base for help with WIPO Sequence.

This includes known issues and how to report bugs.

[Knowledge Base](#)

Download

By downloading and installing WIPO Sequence, you are accepting the following [Terms of Use \(October 2021\)](#).

▼ Select your platform...

- Windows OS (exe)
- Linux (Applmage)
- Mac OSX (dpm)



WIPO sequence authoring tool

- Generate the sequence listing XML file using the “Generate Sequence Listing” button.

WIPO Sequence

SAMPLE ST.26 PROJECT

VERIFICATION REPORT

LANGUAGE DEPENDENT QUALIFIERS

IMPORT REPORT

DISPLAY THE SEQUENCE LISTING

HELP

PREFERENCES

ENGL

Return to project home

GENERAL INFORMATION SEQUENCES

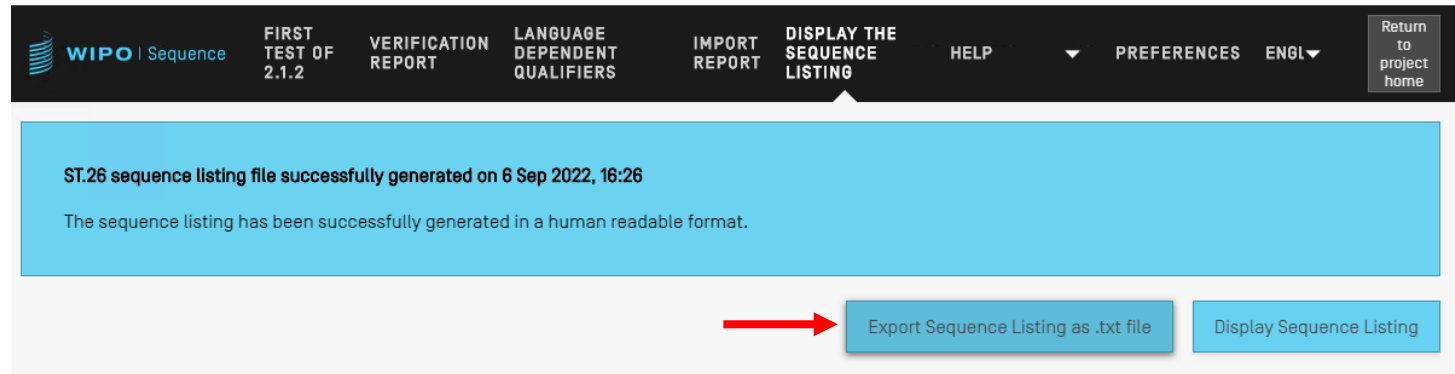
SAMPLE ST.26 P...

Print Export Import Another Project Validate **Generate Sequence Listing**

Project Name Sample ST.26 Project	Creation date 2022-08-12 12:35
Status valid	File Name no adn test
Description	Sequences 11
Original free text language code en	Non English free text language code fr
Automatically add a translation qualifier when a CDS feature is created On	

WIPO sequence authoring tool

- Do not file a “human readable” print out of your project.



The screenshot shows the top navigation bar of the WIPO Sequence tool. The navigation items include: WIPO | Sequence, FIRST TEST OF 2.1.2, VERIFICATION REPORT, LANGUAGE DEPENDENT QUALIFIERS, IMPORT REPORT, DISPLAY THE SEQUENCE LISTING (highlighted with a white triangle), HELP, PREFERENCES, ENGL, and a 'Return to project home' button. Below the navigation bar is a light blue success message box containing the text: 'ST.26 sequence listing file successfully generated on 6 Sep 2022, 16:26' and 'The sequence listing has been successfully generated in a human readable format.' At the bottom of the interface, there are two buttons: 'Export Sequence Listing as .txt file' and 'Display Sequence Listing'. A red arrow points to the 'Export' button.

WIPO sequence authoring tool

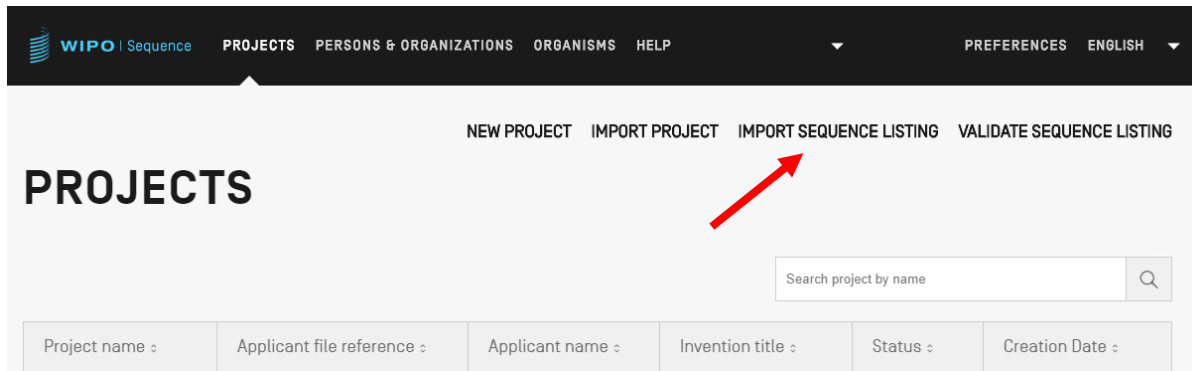
```
File Edit Format View Help
Sequence Listing Information:
  DTD Version: V1_3
  File Name: no adn test.xml
  Software Name: WIPO Sequence
  Software Version: 2.1.2
  Production Date: 2022-09-06
General Information:
  Current application / IP Office: AT
  Current application / Applicant file reference: abc123
  Earliest priority application / IP Office: US
  Earliest priority application / Application number: 61234567
  Earliest priority application / Filing date: 2021-06-27
  Applicant name: Biotech, Inc.
  Applicant name / Language: en
  Invention title: ST.26 Listage des séquences de formation ( fr )
  Invention title: 2.1.2 Test ( en )
  Sequence Total Quantity: 11
Sequences:
  Sequence Number (ID): 1
  Length: 2100
  Molecule Type: DNA
  Features Location/Qualifiers:
    - source, 1..2100
      > mol_type, genomic DNA
      > organism, Saccharomyces cerevisiae
      > strain, strain SCM1
    - CDS, 1..300
      > protein_id, 2
      > translation,
MDNEEVNEECMRLFFKNARAHLDKHLTSRLTCDENAYITFRCLDGIHRKSTRFLELLLKQENMYHNMNYERINDSVIPLVLKLLWLQI
HEPTLQWFEH
Residues:
atggataatg aagaagtaa cgaagaatgt atgagattat ttttcaagaa cgctcgtgcg 60
catctggata aacatctaac atcaaggttg acatcgcgatg aaaaatgcata tatcacgttc 120
agatgcttcc tggatggaat acatcgcgaaa tctactaggt ttctcgaaga gctacttttg 180
aaacaagaaa atatgtacca taataacaat tacgaacgca taaatgattc cgtgatacca 240
ttggttctga aacttttatg gcttcaaatt cacgaaccta cactccaatg gtttgagcac 300
tggttccatg atatcatcgc actaagtaac agaagaaagt tcagagtttt tagaatTTTT 360
*****
```

- This is a “human readable” print out of project data; it is NOT a sequence listing!
- This text file should not be filed at a patent office; it is for applicant use only.



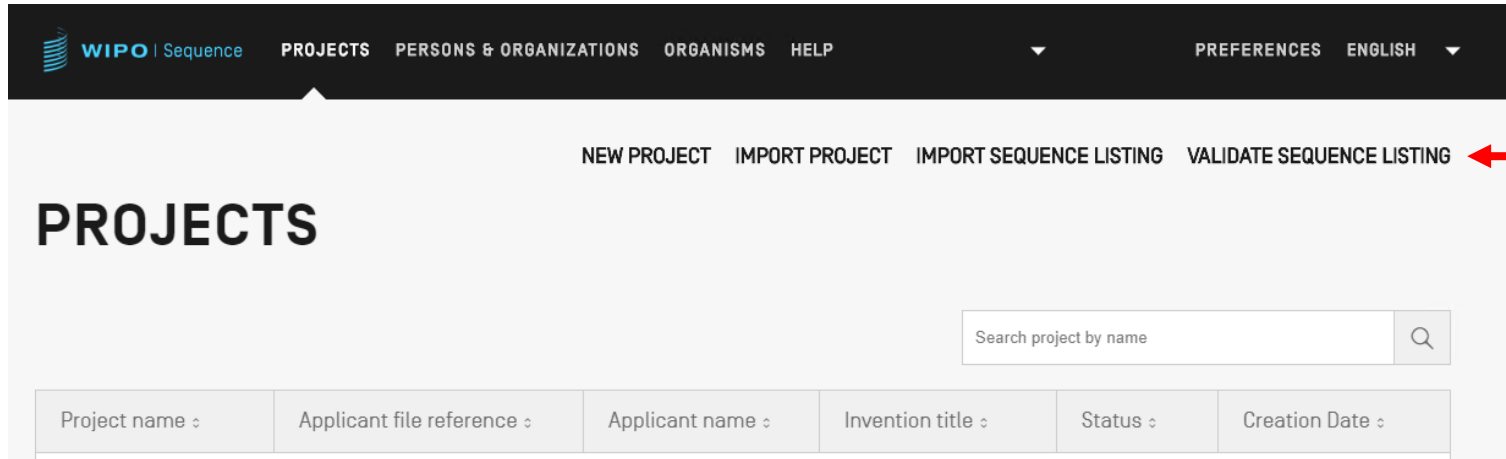
WIPO sequence authoring tool

- **DO NOT** manually edit your XML file after generation.
- Make any changes within the project, and then use the “Generate Sequence Listing” button to create a new XML file.
- If you don’t have the original project used to create the XML file, you can use the “Import Sequence Listing” function to create a new project by importing an XML.



WIPO sequence authoring tool

- Always validate your XML file after generation before filing.

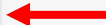


The screenshot displays the WIPO Sequence tool interface. At the top, a dark navigation bar contains the WIPO logo and the text 'WIPO | Sequence'. Below this, a menu bar lists 'PROJECTS', 'PERSONS & ORGANIZATIONS', 'ORGANISMS', and 'HELP'. On the right side of the menu bar, there are options for 'PREFERENCES' and 'ENGLISH'. Below the menu bar, the main content area is titled 'PROJECTS'. In the top right of this area, there are four links: 'NEW PROJECT', 'IMPORT PROJECT', 'IMPORT SEQUENCE LISTING', and 'VALIDATE SEQUENCE LISTING'. A red arrow points to the 'VALIDATE SEQUENCE LISTING' link. Below the links, there is a search bar with the placeholder text 'Search project by name' and a magnifying glass icon. At the bottom, there is a table with six columns: 'Project name', 'Applicant file reference', 'Applicant name', 'Invention title', 'Status', and 'Creation Date'. Each column has a small downward arrow next to its header.

WIPO sequence authoring tool

- **Helpful hint** – import of ST.25 sequence listings with a large number of nucleotide sequences.
- Use the “bulk edit” function to add “mol_type” qualifier values to multiple sequences at once.

▼ SEQUENCES

Create new sequence Import sequence Insert Sequence Reorder Sequence Bulk Edit 

Sequence ID Number	Sequence Name	Length	Molecule Type
1	2_ST26 Training Sequence Listing_seq_1	2100	DNA

WIPO sequence authoring tool

1. Under "Type of bulk edit*" select "Qualifier molecule type";
2. Select the "Molecule Type*";
3. Enter the SEQ ID numbers of the sequence you want to bulk edit;
4. Select the desired "mol_type" qualifier value.

1 → Type of bulk edit* Qualifier molecule type	Select Range of Sequence IDs* ← 3 1,3,5, 8
Select the type of bulk edit to continue Use commas to separate individual sequences (for example: "2,5,8"); use a dash to indicate a range of sequences (for example: "2-8").	
2 → Molecule Type* DNA	Qualifier Molecule Type* ← 4 genomic DNA
Only DNA/RNA sequences allow editing of the qualifier 'mol_type' because for amino acid sequences this qualifier value is automatically set to 'protein'. An error will be generated during project validation for sequences where the organism is specified as 'synthetic construct' and the qualifier value for 'mol_type' is not 'other DNA' or 'other RNA'.	
The qualifier 'mol_type' of hybrid DNA/RNA sequences, where the 'combinedIndicator' = 'Yes', cannot be bulk edited.	
Enter one or more of the following DNA sequences to edit the qualifier 'mol_type'.	

Questions?



Compliance with ST.26 requirements

Compliance with ST.26 requirements

- The “organism” qualifier value must be one of the following options:
 1. A full Latin “Genus species” name or “Genus sp.” (see WIPO ST.26 paragraphs 78-80), wherein the Genus name is capitalized and the species name is lower-case;
 2. A virus name (see WIPO ST.26 paragraph 82);
 3. “unidentified”, for naturally occurring sequences where the Latin Genus and/or species is unknown. Any other taxonomic information should be contained in a “note” qualifier (see WIPO ST.26 paragraph 81); or
 4. “synthetic construct” for sequences that are not naturally occurring (see WIPO ST.26 paragraph 83).

Compliance with ST.26 requirements

- If you use "Genus species" or "Genus sp." for the "organism" qualifier value.
- **DO NOT** abbreviate the Genus name.
 - Staphylococcus aureus ✓
 - S. aureus ✗

Compliance with ST.26 requirements

- If you use "Genus species" or "Genus sp." for the "organism" qualifier value.
- **DO NOT** leave the species name out, or spell out "species."
 - Staphylococcus sp. ✓
 - Staphylococcus ✗
 - Staphylococcus species ✗

Compliance with ST.26 requirements

- If you use “Genus species” or “Genus sp.” for the “organism” qualifier value.
- **DO NOT** include the Genus name in lowercase or the species name in uppercase.
 - Homo sapiens ✓
 - homo sapiens ✗
 - Homo Sapiens ✗

Compliance with ST.26 requirements

- If you use “Genus species” or “Genus sp.” for the “organism” qualifier value.
- **DO NOT** use a taxonomic name that is broader than a Genus.
 - Staphylococcaceae sp. **X**
 - Staphylococcaceae is a Family of bacteria, **NOT** a Genus!
- If the only taxonomic information about the source organism is broader than a genus, use “unidentified” as the “organism” qualifier value and include any known taxonomic information in a “note” qualifier.

Compliance with ST.26 requirements

- If you use “Genus species” or “Genus sp.” for the “organism” qualifier value.
- **DO NOT** include strain, substrain, isolate, or subspecies information.
 - Staphylococcus aureus ✓
 - Staphylococcus aureus strain MRSA252 ✗
- Strain, substrain, isolate, subspecies, cultivar, clone, serovar, cell line, and other source organism information can be included in an appropriate “source” feature qualifier (see WIPO Sequence Annex I, Section 5.37).

Compliance with ST.26 requirements

- Correctly describing modified residues and variant sequences:
 - Modified nucleotides must be described using the feature key "**modified_base**" (ST.26, para. 17);
 - Modified amino acids must be described using the feature key "**MOD_RES**", "**SITE**", "**CARBOHYD**" or "**LIPID**", as appropriate (ST.26, pgh. 30); and
 - Variants must be described using the feature keys "**variation**" or "**misc_difference**" for nucleotide sequences, and "**VAR_SEQ**" or "**VARIANT**" for amino acid sequences (ST.26, para. 96).

Compliance with ST.26 requirements

- **Common mistake:** use of "modified_base" or "misc_feature" to describe a nucleotide sequence variant.

Example disclosure:

5'-aggtcgatggttacgn-3' where n=g, t, c, or i

- The correct feature key to describe the "n" is "variation" or "misc_difference" along with a "note" qualifier with the value "n=g, t, c, or i."
- One of the alternatives is "i", or inosine, which is a modified nucleotide. You can also include a "modified_base" feature key to note that the n may be "i", but it is not necessary.

Compliance with ST.26 requirements

- **Common mistake:** use of "SITE" or "MOD_RES" to describe an amino acid sequence variant.

Example disclosure:

MDCWIKSLSX where X= P, L, I, or V

- The correct feature key to describe the "X" is "VAR_SEQ" or "VARIANT" along with a "note" qualifier with the value "X= P, L, I, or V"

Compliance with ST.26 requirements

- **Common mistake:** use of "misc_feature" or "variation" or "misc_difference" to describe a modified residue

Example disclosure:

5'-aggtcgatgttacgn-3' where n = i (inosine)

- The correct feature key to describe the "n" is "modified_base" along with a "mod_base" qualifier with the value "i."
- One of the alternatives is "i", or inosine, which is a modified nucleotide. You can also include a "modified_base" feature key to note that the n may be "i", but it is not necessary.



Compliance with ST.26 requirements

- **Helpful hint** – describing modified residues at multiple locations within a nucleotide sequence using a single feature key.

Example disclosure:

atggtc*gatgttac*c*c*ggatgtggtc*gatgttaatgttattac*
1 5 10 15 20 25 30 35 40

where c* = 5-methylcytidine

- How can feature keys be used to describe these modified residues?

Compliance with ST.26 requirements

- Method 1 – use a separate feature key to describe each modified cytosine or contiguous span of modified cytosines.

atggtc*gatgtta*c*c*ggatgtggtc*gatgttaatgttattac*
1 5 10 15 20 25 30 35 40

Feature key 1:

"modified_base"
location = 6
qualifier "mod_base"
qualifier value = m5c

Feature key 2:

"modified_base"
location = 14..16
qualifier "mod_base"
qualifier value = m5c

Feature key 3:

"modified_base"
location = 26
qualifier "mod_base"
qualifier value = m5c

Feature key 4:

"modified_base"
location = 43
qualifier "mod_base"
qualifier value = m5c

Compliance with ST.26 requirements

- Method 2 – use a single feature key with an “order” location operator (ST.26 pgh. 67).

atggtc*gatgttac*c*c*ggatgtggtc*gatgttaatgttattac*
1 5 10 15 20 25 30 35 40

Feature key 1:

“modified_base”

location = order(6,14..16,26,43)

qualifier “mod_base”

qualifier value = m5c

- Note that the “order” location operator can only be used for locations in nucleotide sequences.

Questions?



ST.26 sequence listings in international (PCT) applications

ST.26 sequence listings in PCT apps

- A sequence listing (SL) is required as part of the description where the PCT applicant contains nucleotide and/or amino acid sequences.
 - PCT Rule 5.2: “Where the international application contains disclosure of nucleotide and/or amino acid sequences. . . the description shall include a sequence listing part of the description. . .”
- The SL must comply with WIPO Standard ST.26 and the PCT Administrative Instructions.
- A SL CANNOT be text (.TXT) format and CANNOT be filed on sheets of paper or as a separate PDF file.

ST.26 sequence listings in PCT apps

- A SL included with IA on the international filing date (IFD) and indicated as part of the application within Box No. IX of the Request (PCT/RO/101) checklist will form “part of the international application.”
- Filing ST.26 SL using the USPTO electronic filing system, ST.26 SL **must** be filed via **Patent Center**.
 - EFS-Web does not accept ST.26 XML sequence listings. If SL is greater than 100MB, on physical data carrier (disc) labeled “sequence listing” filed on the same day as IA.
- An SL filed with RO/US must be in English only, including any language dependent text.



ST.26 sequence listings in PCT apps

Sheet No.			
Box No. IX CHECK LIST for electronic filing with RO/US – only to be used when filing via the USPTO electronic filing system			
This international application contains the following:	Number of sheets	This international application is accompanied by the following item(s) (mark the applicable check-boxes below and indicate in right column the number of each item):	Number of items
(a) request form PCT/RO/101 (including any declarations and supplemental sheets)	1. <input type="checkbox"/> fee calculation sheet
(b) description	2. <input type="checkbox"/> original separate power of attorney
(c) claims	3. <input type="checkbox"/> original general power of attorney
(d) abstract	4. <input type="checkbox"/> copy of general power of attorney; reference number:
(e) drawings (if any)	5. <input type="checkbox"/> priority document(s) identified in Box No. VI as item(s)
Total number of sheets	0	6. <input type="checkbox"/> Translation of international application into (language):
(f) sequence listing part of the description <input checked="" type="checkbox"/> filed as a WIPO Standard ST.26 XML file <input type="checkbox"/> WILL BE filed separately on physical data carrier(s) as a WIPO Standard ST.26 XML file , on the same day		7. <input type="checkbox"/> separate indications concerning deposited microorganism or other biological material
Indicate type and number of physical data carrier(s)		8. <input type="checkbox"/> copy of results of earlier search(es) (Rule 12bis.1(a))
.....		9. <input type="checkbox"/> other (specify):
.....			
Figure of the drawings which		Language of filing of the	

- The request (PCT/RO/101) must properly identify ST.26 XML file within the checklist (box IX(f)) filed using **Patent Center**.
- **FYI:** new request form for IA filed on/after July 1, 2022 has updated Box No. IX check list (see left).

ST.26 sequence listings in PCT apps

Sheet No.			
Box No. IX	CHECK LIST for electronic filing with RO/US - only to be used when filing via the USPTO electronic filing system		
This international application contains the following:	Number of sheets	This international application is accompanied by the following item(s) (mark the applicable check-boxes below and indicate in right column the number of each item):	Number of items
Total number of sheets	0	6. <input type="checkbox"/> Translation of international application into (language):	
(f) sequence listing part of the description		7. <input type="checkbox"/> separate indications concerning deposited microorganism or other biological material	
<input type="checkbox"/> filed as a WIPO Standard ST.26 XML file		8. <input type="checkbox"/> copy of results of earlier search(es) (Rule 12bis.1(a))	
<input checked="" type="checkbox"/> WILL BE filed separately on physical data carrier(s) as a WIPO Standard ST.26 XML file, on the same day		9. <input type="checkbox"/> other (specify):	
Indicate type and number of physical data carrier(s)	1 optical disc		

Sheet No.			
Box No. IX	CHECK LIST for PAPER filing - only to be used when filing on PAPER		
This international application	Number	This international application is accompanied by the	Number
Total number of sheets	0	<input type="checkbox"/> microorganism or other biological material	
(f) sequence listing part of the description as a WIPO Standard ST.26 XML file (indicate type and number of physical data carrier(s)):	1 optical disc	8. <input type="checkbox"/> copy of results of earlier search(es) (Rule 12bis.1(a))	
		9. <input type="checkbox"/> other (specify):	

- PDF request form has option when filing a sequence listing in an IA with RO/US “forming Part of the international application” submitted on a physical carrier (disc) on the same day as IA.
- PDF request form when IA is filed on paper with SL on physical carrier (disc) (see left).

ST.26 sequence listings in PCT apps

IX	Check list	Number of sheets	Electronic file(s) attached
IX-1	Request (including declaration sheets)		
IX-2	Description		
IX-3	Claims		
IX-4	Abstract		
IX-5	Drawings		
IX-6a	Sequence listing part of the description (also to be used for the purposes of international search)		✓
IX-7	TOTAL		
Accompanying items			
		Paper document(s) attached	Electronic file(s) attached
IX-8	Fee calculation sheet		

- Request form using ePCT to indicate SL is “forming part of the international application” (see left).
- Note:** As of July 2022, WIPO is no longer providing support for PCT-SAFE and applicants should no longer generate a request form using PCT-SAFE.

○ **FYI:** ePCT must be used to generate the new request form.

0-4	Form PCT/RO/101 PCT Request	
0-4-1	Prepared Using	ePCT-Filing for data package download Version
0-5	Petition	The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty

ST.26 sequence listings in PCT apps

- A SL may “form part of the International application,” filed after the IFD where the SL was:
 - included in the application under PCT Rule 20.5(b) or (c), or PCT Rule 20.5*bis*(b) or (c); or
 - considered to have been contained in application under PCT Rule 20.6(b); or
 - corrected under PCT rule 26; or
 - rectified under PCT Rule 91; or
 - added as an amendment under Article 34.

*Amendment under Article 34 requires the filing of a Demand to the International Preliminary Examination Authority (IPEA).

ST.26 sequence listings in PCT apps

- Where sequences are disclosed, but no SL in XML format was provided, the International Searching Authority (ISA) may issue an invitation to furnish Sequence Listing (Form PCT/ISA/225) under PCT rule 13ter.1.
 - SL filed in response to PCT/ISA/225 does “not forming part of the international application” since it is furnished for the purposes of the international search or international preliminary examination.
 - SL filed in response to PCT/ISA/225 must be accompanied by a late furnishing fee under 37 C.F.R. 1.445(a)(5) when filed with ISA/US.
 - SL in response to PCT/ISA/225 must be accompanied by the “a statement to the effect that the sequence listing does not go beyond the disclosure in the international application as filed.”
 - Time period for reply to the PCT/ISA/225 is one month and is NOT extendable .
 - Failure to timely response to the PCT/ISA/225 may result in search and examination by the ISA to the extent that a meaningful search can be carried out without the sequence listing under PCT (Rule 13ter.1(d)).
 - SL in response to PCT/ISA/225 must be filed with the chosen ISA.
 - IF ISA is US, SL can be filed using Patent Center or if SL is greater than 100MB, on physical data carrier (disc).

**ST.26 sequence listings in
U.S. national stage applications (35
U.S.C §371)**

ST.26 sequence listings in §371 apps

- A SL in a U.S. national stage application under 35 U.S.C. §371 must be in compliance with 37 C.F.R. §1.831-1.835
- Where the ST.26 sequence listing XML forms part of the international application and the international publication has occurred, the USPTO will obtain the ST.26 sequence listing XML as part of the Article 20 documents from the International Bureau for the national stage application.
 - Where sequence listing formed part of the IA and the USPTO obtain the ST.26 sequence listing XML as part of the Article 20 documents, an incorporation by reference, under 37 C.F.R. 1.834(c), is NOT required in the 35 U.S.C. §371 application.
 - Where the ST.26 SL XML formed part of the international application, applicant should not provide a SL in the U.S. National Stage upon filing the U.S. National Stage application.
 - A SL provided under PCT Rule 13^{ter}.1 in the IA is does “not forming part of the international application” and will not be retrieved by the USPTO.

ST.26 sequence listings in §371 apps

- **Only** four circumstances under which an ST.26 sequence listing XML should be submitted at time of entry into national phase under 35 U.S.C. 371.
 1. The international phase application (PCT) discloses sequences but does not contain a sequence listing as “forming part of the international application” (Annex C of the Administrative Instructions under the PCT), as required under PCT Rule 5.2(a); or
 2. The international phase application (PCT) discloses sequences and contains a sequence listing as “forming part of the international application”, as required under PCT Rule 5.2(a), but the PCT application was neither filed with the USPTO as receiving Office nor published by the International Bureau at the time of entry; or
 3. A translation of the sequence listing as “forming part of the international application” is necessary because the values of one or more qualifiers that contain language-dependent free text were not provided in English in the ST.26 sequence listing XML of the PCT application; or
 4. Applicant desires to amend the sequence listing as “forming part of the international application”.

ST.26 sequence listings in §371 apps

- Where sequences are disclosed, but no SL in XML format was provided in the U.S. national stage application or the SL contained in the U.S. national stage application is not in compliance with 37 C.F.R. §1.831-1.834, the Office will issue “Notification to Comply With Requirements for Patent Applications Containing Nucleotide And/Or Amino acid Sequence Disclosure,” specifying that 37 CFR 1.831-1.835 apply to the present application and compliance is required.

ST.26 sequence listings in §371 apps

- A ST.26 sequence listing XML submitted in response to a “Notification to Comply With Requirements for Patent Applications Containing Nucleotide And/Or Amino acid Sequence Disclosure,” or as an addition to the application, or to replace an existing SL in the application is an amendment.
- The submission must be compliance with 37 C.F.R. 1.835(a) or (b).
 - Must include an Incorporation by reference statement in a substitute specification in compliance with 37 CFR 1.52, 1.121(b)(3), and 1.125 consisting of:
 - A copy of the previously-submitted specification, with deletions shown with strikethrough or brackets and insertions shown with underlining (marked-up version);
 - A copy of the amended specification without markings (clean version); and
 - A statement that the substitute specification contains no new matter.
- A translated sequence listing XML is not considered and added or amended submission (37 CFR 1.835(d)(2)).

Questions?



ST.26 resources

USPTO Resources

- Sequence Listing Resource Center:
<https://www.uspto.gov/patents/apply/sequence-listing-resource-center>
- Sequence Listing Help Desk via SequenceHelpDesk@USPTO.GOV or 571-272-2510
- PCT Help Desk via 571-272-4300
- Patent Legal Administration Help Desk via 571-272-7701

WIPO Resources

- Recorded training sessions:
https://www.wipo.int/meetings/en/topic.jsp?group_id=330&items=30
- WIPO Standard ST.26 Knowledge Base:
<https://www3.wipo.int/confluence/display/WSSKB/WIPO+Sequence+and+ST.26+Knowledge+Base+Home>



