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WIPO Standard ST.26 (for sequence listings) Introduction

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June 2021

Objectives

- What is a sequence listing?
- INSDC Sequence Databases
- Benefits of WIPO ST.26
- ST.25 vs. ST.26 – what are the differences?
- Transition to ST.26
- XML Basics
- ST.26 Basics – parts of a sequence listing
- Contents of WIPO ST.26
- Introduction to WIPO Sequence

What is a sequence listing?

A sequence listing, as a separate part of the disclosure:

- Contains nucleotide and/or amino acid sequences disclosed in a patent application.
- Includes descriptive information about each sequence.
- Conforms to the requirements of the relevant WIPO Standard.
- Allows for the sequence data of an invention to be searchable.
  - Inside an IP Office.
  - In publically available databases (INSDC databases).

Background - INSDC

- INSDC: International Nucleotide Sequence Database Collaboration:
  - DDBJ: DNA Databank of Japan
  - EMBL-EBI: The European Bioinformatics Institute
  - NCBI: National Center for Biotechnology Information (GenBank)

- IP Offices that submit published/issued application sequence data to INSDC databases include:
  - European Patent Office
  - Japanese Patent Office
  - Korean Intellectual Property Office
  - United States Patent and Trademark Office

- INSDC databases are publicly searchable.

Why WIPO ST.26?

- ST.25 format is not compatible with INSDC requirements, so data is lost when entered into public databases.
- ST.25 rules are not precise, and IP Offices worldwide interpret and enforce the rules differently.
- Certain sequence types that are common today are not covered by ST.25 rules (nucleotide analogs, D-amino acids, branched sequences) and therefore are not present in searchable databases.
- Data is unstructured – ST.25 format is difficult to use for automated validation and data exchange.

WIPO ST.26 benefits

- Acceptance of a single sequence listing worldwide*.
- Standard serves as guidance to ensure agreement amongst IP Offices on application of sequence rules.
- Clarifies what sequence disclosures are required or permitted to be included in a sequence listing, and how these sequences must be represented.
- Enhanced submission quality due to the structure of XML sequence listings.
- Increased automation of data validation and streamlined processing by IP Offices.

* except for required translations of language dependent free text qualifiers into the language of filing for certain IP Offices, which may require replacement sequence listings.

WIPO ST.26 benefits (cont.)

- Data compatibility with the INSDC (International Sequence Database Collaboration*) requirements, namely sequence annotations and organism names will be included in publically searchable databases
- Standardization of feature keys, feature locations, qualifiers and qualifier values, and sequence variant presentation
- Requirement for inclusion of additional types of sequences (nucleotide analogs, D-amino acids, branched sequences) means more sequence data will be searchable

*INSDC includes the DNA Databank of Japan (DDBJ), the European Bioinformatics Institute (EMBL-EBI), and the National Center for Biotechnology Information (NCBI or GenBank); these databases are publicly searchable, free and utilized by EPO, JPO, KIPO, and USPTO.

WIPO ST.25 versus ST.26

ST.25	ST.26
ASCII .txt with numeric identifiers	XML with elements and attributes
Not required to include: - D-amino acids - Linear portions of branched sequences - Nucleotide analogs	Must include: - D-amino acids - Linear portions of branched sequences - Nucleotide analogs
Annotation of sequences: - Feature keys only	Annotation of sequences: - Feature keys and qualifiers
Permitted to include sequences: - < 10 specifically defined nucleotides - < 4 specifically defined amino acids	Prohibited sequences: - < 10 specifically defined nucleotides - < 4 specifically defined amino acids

WIPO ST.25 versus ST.26

general information

ST.25	ST.26
ALL priority application information may be included	ONLY the earliest priority application can be included
ALL applicant and inventor names may be included	ONLY one applicant AND optionally ONE inventor may be included
One invention title permitted	Multiple invention titles permitted, each one in a different language
Applicant/inventor names and invention titles must be in basic Latin characters	Applicant/inventor names may be included using any valid Unicode character along with a basic Latin translation or transliteration

WIPO ST.25 versus ST.26

sequence data

ST.25	ST.26
Sequences identified as DNA, RNA, or PRT only	Sequences identified as DNA, RNA, or AA along with a mandatory mol_type qualifier to further describe the molecule
Organism names: - Latin genus/species - Virus name - "artificial sequence" - "unknown"	Organisms names: - Latin genus/species - Virus name - "synthetic construct" - "unidentified"
"u" represents uracil in nucleotide sequences	"t" represents uracil in RNA sequences and thymine in DNA sequences
Amino acid sequences represented by three letter abbreviations	Amino acid sequences represented by one letter abbreviations

WIPO ST.25 versus ST.26

sequence data (cont.)

ST.25	ST.26
“n” and “Xaa” variables must have a definition provided in a feature	Default value assumed for “n” and “X” variables with no definition
Feature location format not clearly defined	Strictly defined feature location formats; permits use of “<” and “>” in all sequence types, and “^”, “join”, “order”, and “complement” in nucleotide sequences
“Mixed mode” sequences permitted – nucleotide sequence with amino acid translation shown below	NO “mixed mode”; nucleotide translations are included in “translation” qualifiers only

WIPO ST.26: transition to ST.26

- CWS/5 agreed to a transition date of **January 1, 2022**.
- **All** Intellectual Property Offices (IPOs) will transition simultaneously at the international (PCT), national, and regional levels.
- The international filing date (IFD) will be the reference date that determines if an application falls under ST.25 or ST.26 sequence rules, NOT the priority date.
  - Note: ST.25 will remain effective for applications with a filing date prior to January 1, 2022.

WIPO ST.26: basics

What sequences must be included in a sequence listing?

What is a “specifically defined” nucleotide or amino acid?

- “specifically defined” means any nucleotide other than those represented by the symbol “n” and any amino acid other than those represented by the symbol “X”, listed in Annex I. (WIPO Standard ST.26, pgh. 3(m))
- only “specifically defined” residues count towards the minimum length requirement:
  - 10 or more specifically defined nucleotides; or,
  - 4 or more specifically defined amino acids

  - 5’- a<u>n</u>ctggcaa<u>n</u> – 3’ only 8 specifically defined nucleotides; <u>must not</u> be included in a sequence listing
  - 5’- agctggcaat – 3’ ten specifically defined nucleotides; <u>must</u> be included in a sequence listing

WIPO ST.26: basics

What sequences must be included in a sequence listing?

- Nucleotide sequences:
  - 10 or more "specifically defined" and "enumerated"* residues.
  - Include sequences with nucleotide analogs such as peptide nucleic acids (PNAs) and glycol nucleic acids (GNAs).
- Amino acid sequences:
  - 4 or more "specifically defined" and "enumerated" residues.
  - Include sequences with D-amino acids.
  - Linear regions of branched sequences are required to be included in a sequence listing.

* Definitions of "specifically defined" and "enumerated" can be found in WIPO Standard ST.26, pgh. 3; examples applying these definitions to real-world examples can be found in WIPO Standard ST.26, Annex VI.

WIPO ST.26: basics

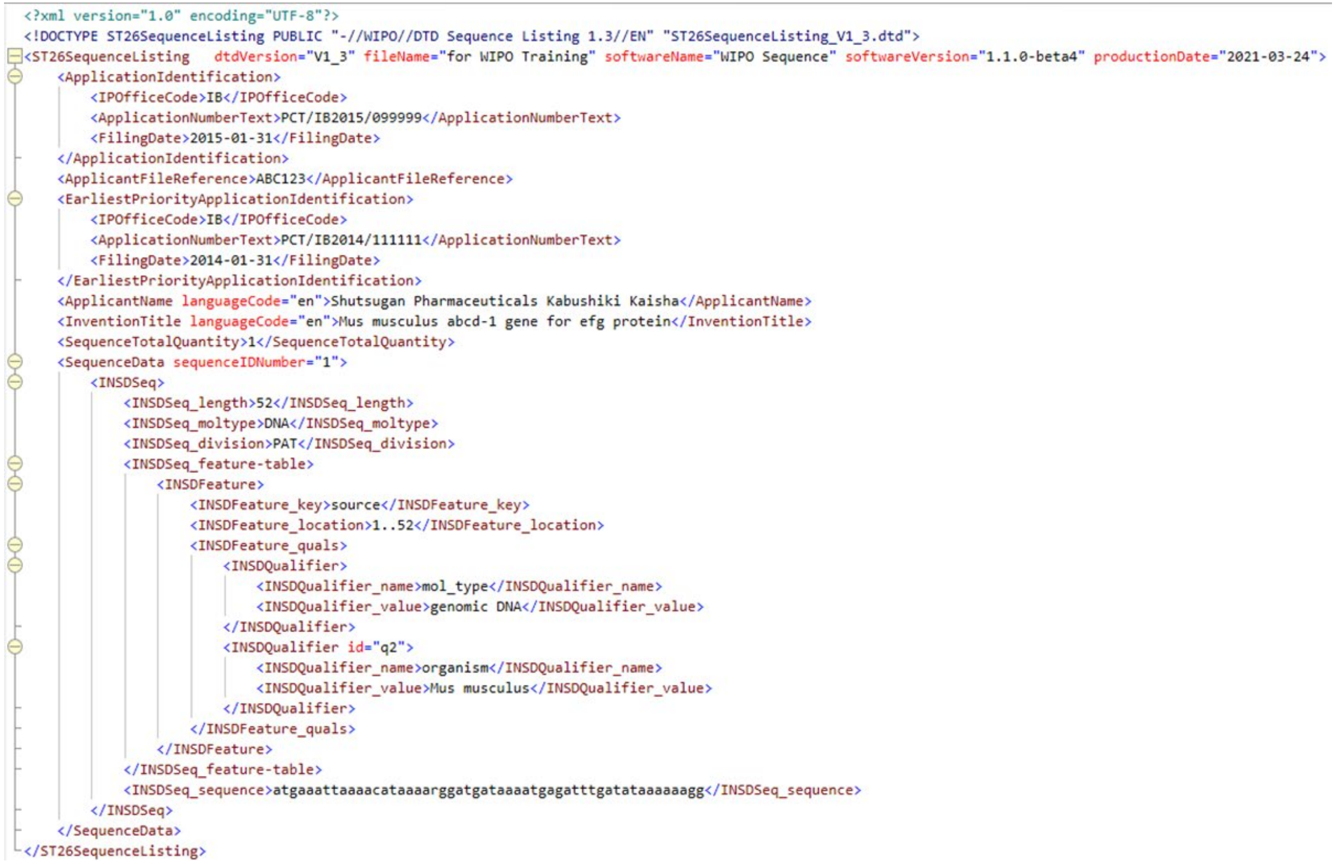
- Must be presented in XML 1.0.
- Must validate against the WIPO ST.26 DTD (Annex II).
- Must be contained in one file.
- Must be encoded using Unicode UTF-8.
- Structure of the Sequence Listing:
  XML declaration
  Document type (DOCTYPE) declaration
  Root element
    - General information part
    - Sequence data part

XML basics

- XML = eXtensible Markup Language
- Information is ‘tagged’ using descriptive elements and attributes.
- Standardized means of data exchange that is human and machine readable.
- DTD = Document Type Definition - defines the structure and the legal elements and attributes of an XML document.
- Sequence listings in ST.26 XML format must validate against the ST.26 DTD (Annex II).

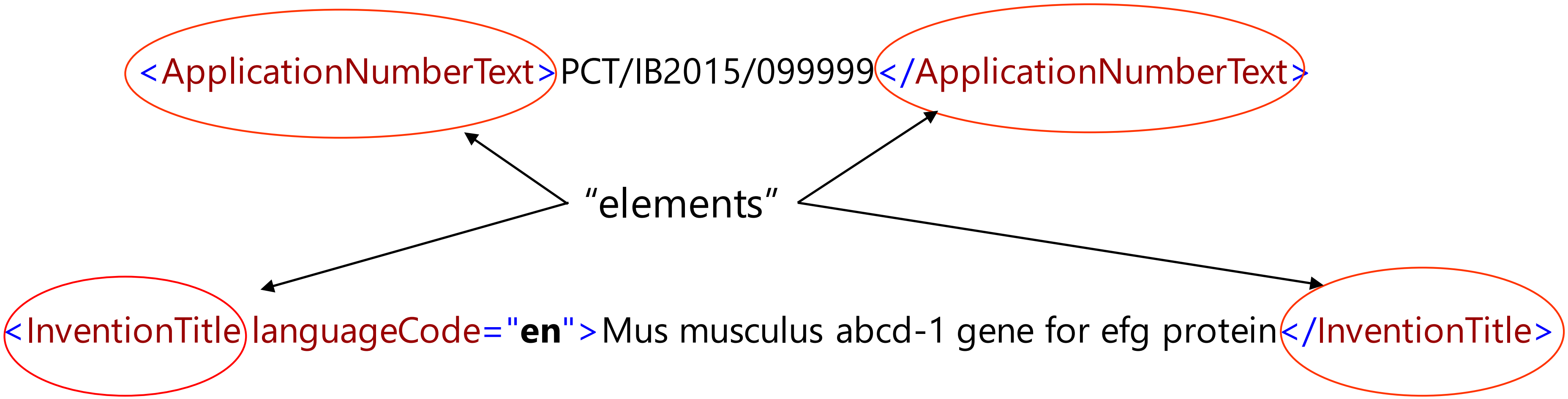
XML basics

example ST.26 XML sequence listing



```xml
<?xml version="1.0" encoding="UTF-8"?>
<!DOCTYPE ST26SequenceListing PUBLIC "-//WIPO//DTD Sequence Listing 1.3//EN" "ST26SequenceListing_V1_3.dtd">
<ST26SequenceListing  dtdVersion="V1_3" fileName="for WIPO Training" softwareName="WIPO Sequence" softwareVersion="1.1.0-beta4" productionDate="2021-03-24">
    <ApplicationIdentification>
        <IPOfficeCode>IB</IPOfficeCode>
        <ApplicationNumberText>PCT/IB2015/099999</ApplicationNumberText>
        <FilingDate>2015-01-31</FilingDate>
    </ApplicationIdentification>
    <ApplicantFileReference>ABC123</ApplicantFileReference>
    <EarliestPriorityApplicationIdentification>
        <IPOfficeCode>IB</IPOfficeCode>
        <ApplicationNumberText>PCT/IB2014/111111</ApplicationNumberText>
        <FilingDate>2014-01-31</FilingDate>
    </EarliestPriorityApplicationIdentification>
    <ApplicantName languageCode="en">Shutsugan Pharmaceuticals Kabushiki Kaisha</ApplicantName>
    <InventionTitle languageCode="en">Mus musculus abcd-1 gene for efg protein</InventionTitle>
    <SequenceTotalQuantity>1</SequenceTotalQuantity>
    <SequenceData sequenceIDNumber="1">
        <INSDSeq>
            <INSDSeq_length>52</INSDSeq_length>
            <INSDSeq_moltype>DNA</INSDSeq_moltype>
            <INSDSeq_division>PAT</INSDSeq_division>
            <INSDSeq_feature-table>
                <INSDFeature>
                    <INSDFeature_key>source</INSDFeature_key>
                    <INSDFeature_location>1..52</INSDFeature_location>
                    <INSDFeature_quals>
                        <INSDQualifier>
                            <INSDQualifier_name>mol_type</INSDQualifier_name>
                            <INSDQualifier_value>genomic DNA</INSDQualifier_value>
                        </INSDQualifier>
                        <INSDQualifier id="q2">
                            <INSDQualifier_name>organism</INSDQualifier_name>
                            <INSDQualifier_value>Mus musculus</INSDQualifier_value>
                        </INSDQualifier>
                    </INSDFeature_quals>
                </INSDFeature>
            </INSDSeq_feature-table>
            <INSDSeq_sequence>atgaaattaaaacataaaarggatgataaaatgagatttgatataaaaaagg</INSDSeq_sequence>
        </INSDSeq>
    </SequenceData>
</ST26SequenceListing>
```

XML basics
elements, attributes, and values



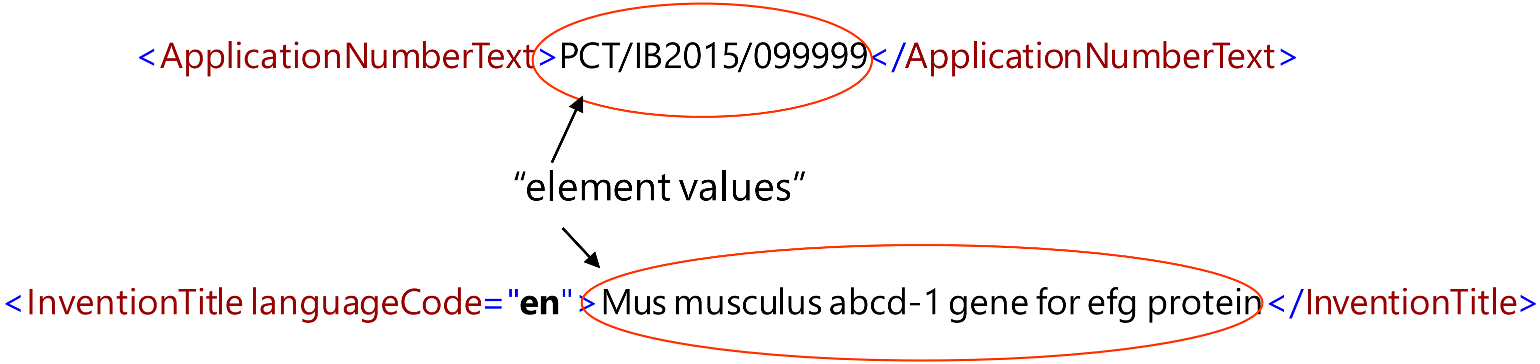
```
<ApplicationNumberText>PCT/IB2015/099999</ApplicationNumberText>
```

“elements”

```
<InventionTitle languageCode="en">Mus musculus abcd-1 gene for efg protein</InventionTitle>
```

XML basics

elements, attributes, and values



```
<ApplicationNumberText>PCT/IB2015/099999</ApplicationNumberText>
```

“element values”

```
<InventionTitle languageCode="en">Mus musculus abcd-1 gene for efg protein</InventionTitle>
```

XML basics

elements, attributes, and values

```
<ApplicationNumberText>PCT/IB2015/099999</ApplicationNumberText>
```

“attribute”

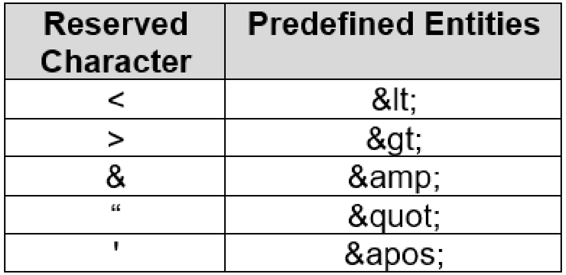
```
<InventionTitle languageCode="en">Mus musculus abcd-1 gene for efg protein</InventionTitle>
```

“attribute value”

XML basics

reserved characters

Must be replaced by their predefined entities in an element value.



Reserved Character	Predefined Entities
<	<
>	>
&	&
“	"
'	'

(from WIPO Standard ST.26, pgh. 41)

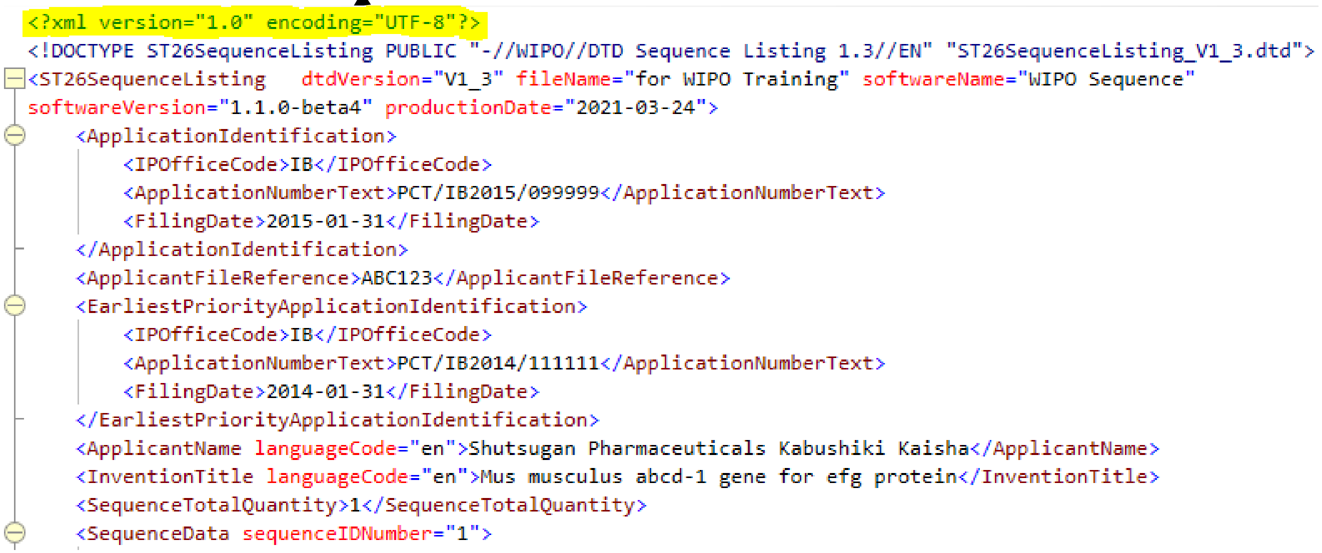
Example: Desired feature location is “<50..62”

<INSDFeature_location><50..62</INSDFeature_location> ✗

<INSDFeature_location><50..62</INSDFeature_location> ✓

WIPO ST.26: basics
parts of an ST.26 XML sequence listing

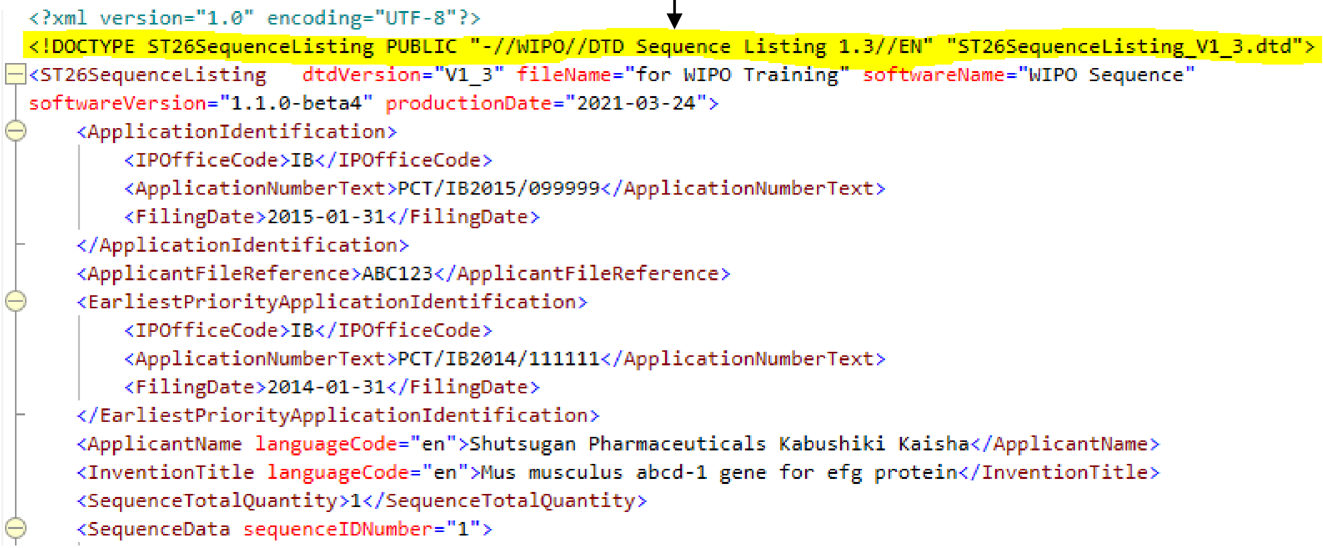
Line 1 – the XML declaration
(ST.26 pgh. 39(a))



```
<?xml version="1.0" encoding="UTF-8"?>
<!DOCTYPE ST26SequenceListing PUBLIC "-//WIPO//DTD Sequence Listing 1.3//EN" "ST26SequenceListing_V1_3.dtd">
<ST26SequenceListing  dtdVersion="V1_3" fileName="for WIPO Training" softwareName="WIPO Sequence"
softwareVersion="1.1.0-beta4" productionDate="2021-03-24">
    <ApplicationIdentification>
        <IPOfficeCode>IB</IPOfficeCode>
        <ApplicationNumberText>PCT/IB2015/099999</ApplicationNumberText>
        <FilingDate>2015-01-31</FilingDate>
    </ApplicationIdentification>
    <ApplicantFileReference>ABC123</ApplicantFileReference>
    <EarliestPriorityApplicationIdentification>
        <IPOfficeCode>IB</IPOfficeCode>
        <ApplicationNumberText>PCT/IB2014/111111</ApplicationNumberText>
        <FilingDate>2014-01-31</FilingDate>
    </EarliestPriorityApplicationIdentification>
    <ApplicantName languageCode="en">Shutsugan Pharmaceuticals Kabushiki Kaisha</ApplicantName>
    <InventionTitle languageCode="en">Mus musculus abcd-1 gene for efg protein</InventionTitle>
    <SequenceTotalQuantity>1</SequenceTotalQuantity>
    <SequenceData sequenceIDNumber="1">
```

WIPO ST.26: basics
parts of an ST.26 XML sequence listing

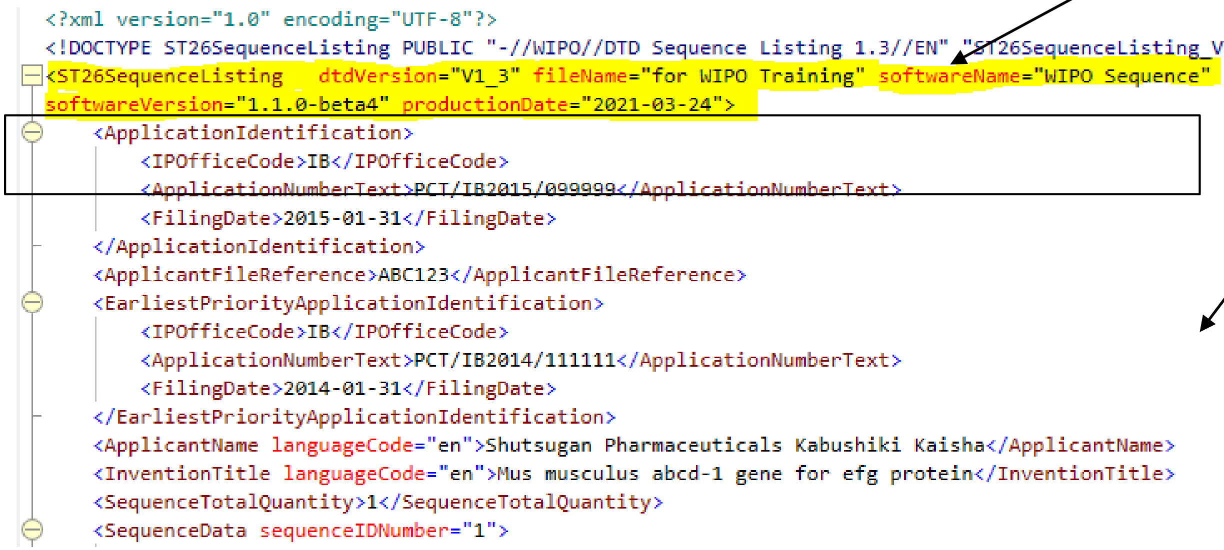
Line 2 – the document type (DOCTYPE) declaration
(ST.26 pgh. 39(b))



```
<?xml version="1.0" encoding="UTF-8"?>
<!DOCTYPE ST26SequenceListing PUBLIC "-//WIPO//DTD Sequence Listing 1.3//EN" "ST26SequenceListing_V1_3.dtd">
<ST26SequenceListing   dtdVersion="V1_3" fileName="for WIPO Training" softwareName="WIPO Sequence"
softwareVersion="1.1.0-beta4" productionDate="2021-03-24">
    <ApplicationIdentification>
        <IPOfficeCode>IB</IPOfficeCode>
        <ApplicationNumberText>PCT/IB2015/099999</ApplicationNumberText>
        <FilingDate>2015-01-31</FilingDate>
    </ApplicationIdentification>
    <ApplicantFileReference>ABC123</ApplicantFileReference>
    <EarliestPriorityApplicationIdentification>
        <IPOfficeCode>IB</IPOfficeCode>
        <ApplicationNumberText>PCT/IB2014/111111</ApplicationNumberText>
        <FilingDate>2014-01-31</FilingDate>
    </EarliestPriorityApplicationIdentification>
    <ApplicantName languageCode="en">Shutsugan Pharmaceuticals Kabushiki Kaisha</ApplicantName>
    <InventionTitle languageCode="en">Mus musculus abcd-1 gene for efg protein</InventionTitle>
    <SequenceTotalQuantity>1</SequenceTotalQuantity>
    <SequenceData sequenceIDNumber="1">
```

WIPO ST.26: basics
parts of an ST.26 XML sequence listing

Line 3 – the root element
(ST.26 pgh. 43)



```
<?xml version="1.0" encoding="UTF-8"?>
<!DOCTYPE ST26SequenceListing PUBLIC "-//WIPO//DTD Sequence Listing 1.3//EN" "ST26SequenceListing_V1_3.dtd">
<ST26SequenceListing  dtdVersion="V1_3" fileName="for WIPO Training" softwareName="WIPO Sequence"
softwareVersion="1.1.0-beta4" productionDate="2021-03-24">
    <ApplicationIdentification>
        <IPOfficeCode>IB</IPOfficeCode>
        <ApplicationNumberText>PCT/IB2015/099999</ApplicationNumberText>
        <FilingDate>2015-01-31</FilingDate>
    </ApplicationIdentification>
    <ApplicantFileReference>ABC123</ApplicantFileReference>
    <EarliestPriorityApplicationIdentification>
        <IPOfficeCode>IB</IPOfficeCode>
        <ApplicationNumberText>PCT/IB2014/111111</ApplicationNumberText>
        <FilingDate>2014-01-31</FilingDate>
    </EarliestPriorityApplicationIdentification>
    <ApplicantName languageCode="en">Shutsugan Pharmaceuticals Kabushiki Kaisha</ApplicantName>
    <InventionTitle languageCode="en">Mus musculus abcd-1 gene for efg protein</InventionTitle>
    <SequenceTotalQuantity>1</SequenceTotalQuantity>
    <SequenceData sequenceIDNumber="1">
```

The "general information part"

(ST.26 pghs. 38(a), 45-49)

WIPO ST.26: basics
parts of an ST.26 XML sequence listing

```
    <SequenceData sequenceIDNumber="1">
        <INSDSeq>
            <INSDSeq_length>52</INSDSeq_length>
            <INSDSeq_moltype>DNA</INSDSeq_moltype>
            <INSDSeq_division>PAT</INSDSeq_division>
            <INSDSeq_feature-table>
                <INSDFeature>
                    <INSDFeature_key>source</INSDFeature_key>
                    <INSDFeature_location>1..52</INSDFeature_location>
                    <INSDFeature_quals>
                        <INSDQualifier>
                            <INSDQualifier_name>mol_type</INSDQualifier_name>
                            <INSDQualifier_value>genomic DNA</INSDQualifier_value>
                        </INSDQualifier>
                        <INSDQualifier id="q2">
                            <INSDQualifier_name>organism</INSDQualifier_name>
                            <INSDQualifier_value>Mus musculus</INSDQualifier_value>
                        </INSDQualifier>
                    </INSDFeature_quals>
                </INSDFeature>
            </INSDSeq_feature-table>
            <INSDSeq_sequence>atgaaattaaaacataaaarggatgataaaatgagatttgatataaaaaagg</INSDSeq_sequence>
        </INSDSeq>
    </SequenceData>
</ST26SequenceListing>
```

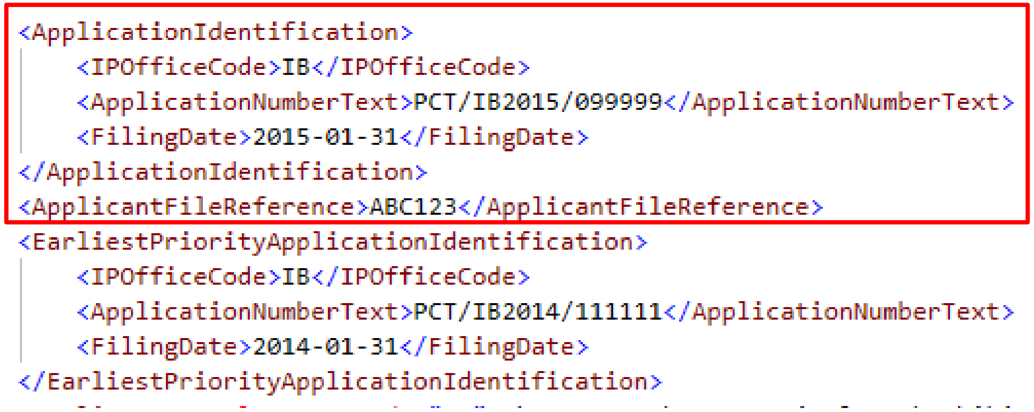
The “sequence data part”

(ST.26 pghs. 38(b), 50-100)

WIPO ST.26: basics
the “general information part”

The “Application Identification” section:

- Application number, filing date, and IP office code are mandatory if known;
- Otherwise, just the applicant file reference is sufficient.

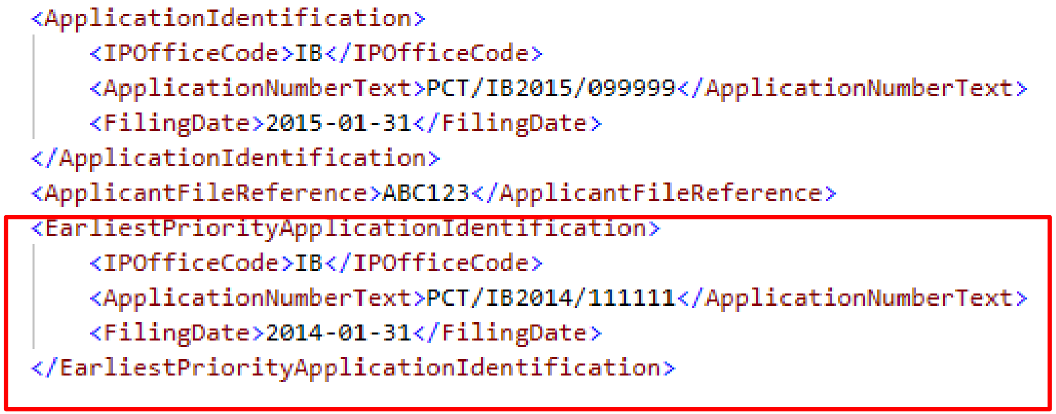


```
<ApplicationIdentification>
    <IPOfficeCode>IB</IPOfficeCode>
    <ApplicationNumberText>PCT/IB2015/099999</ApplicationNumberText>
    <FilingDate>2015-01-31</FilingDate>
</ApplicationIdentification>
<ApplicantFileReference>ABC123</ApplicantFileReference>
<EarliestPriorityApplicationIdentification>
    <IPOfficeCode>IB</IPOfficeCode>
    <ApplicationNumberText>PCT/IB2014/111111</ApplicationNumberText>
    <FilingDate>2014-01-31</FilingDate>
</EarliestPriorityApplicationIdentification>
```

WIPO ST.26: basics
the “general information part” (cont.)

The “Priority Application” section:

- Only one priority application can be included in the sequence listing, and it must be the earliest priority application;
- Mandatory where priority is claimed.



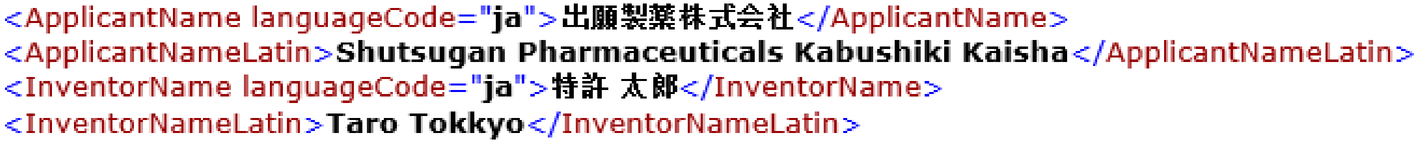
```
<ApplicationIdentification>
    <IPOfficeCode>IB</IPOfficeCode>
    <ApplicationNumberText>PCT/IB2015/099999</ApplicationNumberText>
    <FilingDate>2015-01-31</FilingDate>
</ApplicationIdentification>
<ApplicantFileReference>ABC123</ApplicantFileReference>
<EarliestPriorityApplicationIdentification>
    <IPOfficeCode>IB</IPOfficeCode>
    <ApplicationNumberText>PCT/IB2014/111111</ApplicationNumberText>
    <FilingDate>2014-01-31</FilingDate>
</EarliestPriorityApplicationIdentification>
```

WIPO ST.26: basics

the “general information part” (cont.)

The “Applicant and Inventor Name” section:

- Only one applicant name and one inventor name may be included in the sequence listing, and they must be the “primary” applicant and inventor;
- Applicant name is mandatory; inventor name is optional;
- A language code for applicant and inventor names is mandatory;
- If the applicant and/or inventor name contains non-Unicode Basic Latin characters, then a transliteration or translation into Basic Latin characters must be included.

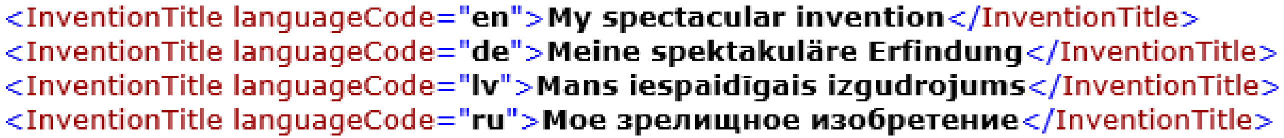


```xml
<ApplicantName languageCode="ja">出願製薬株式会社</ApplicantName>
<ApplicantNameLatin>Shutsugan Pharmaceuticals Kabushiki Kaisha</ApplicantNameLatin>
<InventorName languageCode="ja">特許 太郎</InventorName>
<InventorNameLatin>Taro Tokkyo</InventorNameLatin>
```

WIPO ST.26: basics
the “general information part” (cont.)

The “Invention Title” section:

- At least one invention title in the language of filing is mandatory;
- Additional titles in other languages may be included;
- A language code is mandatory for each title.



```
<InventionTitle languageCode="en">My spectacular invention</InventionTitle>
<InventionTitle languageCode="de">Meine spektakuläre Erfindung</InventionTitle>
<InventionTitle languageCode="lv">Mans iespaidīgais izgudrojums</InventionTitle>
<InventionTitle languageCode="ru">Мое зрелищное изобретение</InventionTitle>
```

WIPO ST.26: basics the “general information part” (cont.)

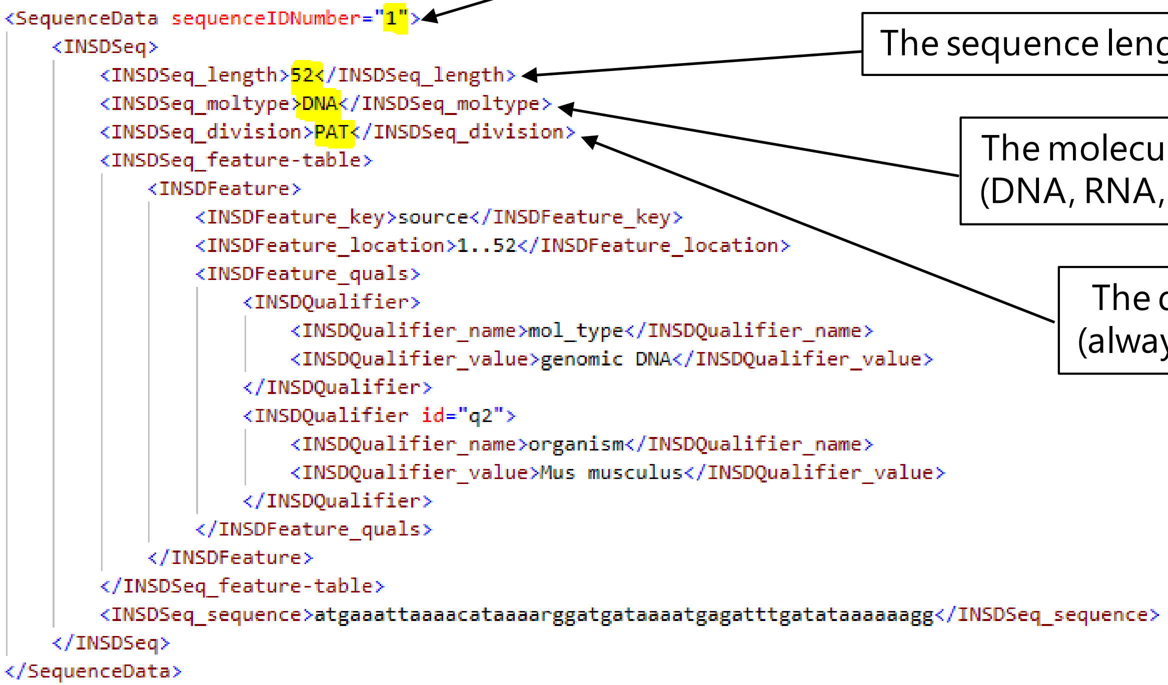
The “Sequence Total Quantity” element:

- Mandatory;
- The total must include skipped sequences.

```xml
<SequenceTotalQuantity>6</SequenceTotalQuantity>
```

WIPO ST.26: basics
the “sequence data part”

Mandatory elements



```
<SequenceData sequenceIDNumber="1">
    <INSDSeq>
        <INSDSeq_length>52</INSDSeq_length>
        <INSDSeq_moltype>DNA</INSDSeq_moltype>
        <INSDSeq_division>PAT</INSDSeq_division>
        <INSDSeq_feature-table>
            <INSDFeature>
                <INSDFeature_key>source</INSDFeature_key>
                <INSDFeature_location>1..52</INSDFeature_location>
                <INSDFeature_quals>
                    <INSDQualifier>
                        <INSDQualifier_name>mol_type</INSDQualifier_name>
                        <INSDQualifier_value>genomic DNA</INSDQualifier_value>
                    </INSDQualifier>
                    <INSDQualifier id="q2">
                        <INSDQualifier_name>organism</INSDQualifier_name>
                        <INSDQualifier_value>Mus musculus</INSDQualifier_value>
                    </INSDQualifier>
                </INSDFeature_quals>
            </INSDFeature>
        </INSDSeq_feature-table>
        <INSDSeq_sequence>atgaaattaaaacataaaarggatgataaaatgagatttgatataaaaaagg</INSDSeq_sequence>
    </INSDSeq>
</SequenceData>
```

The “Sequence Identification Number” or “SEQ ID NO:”

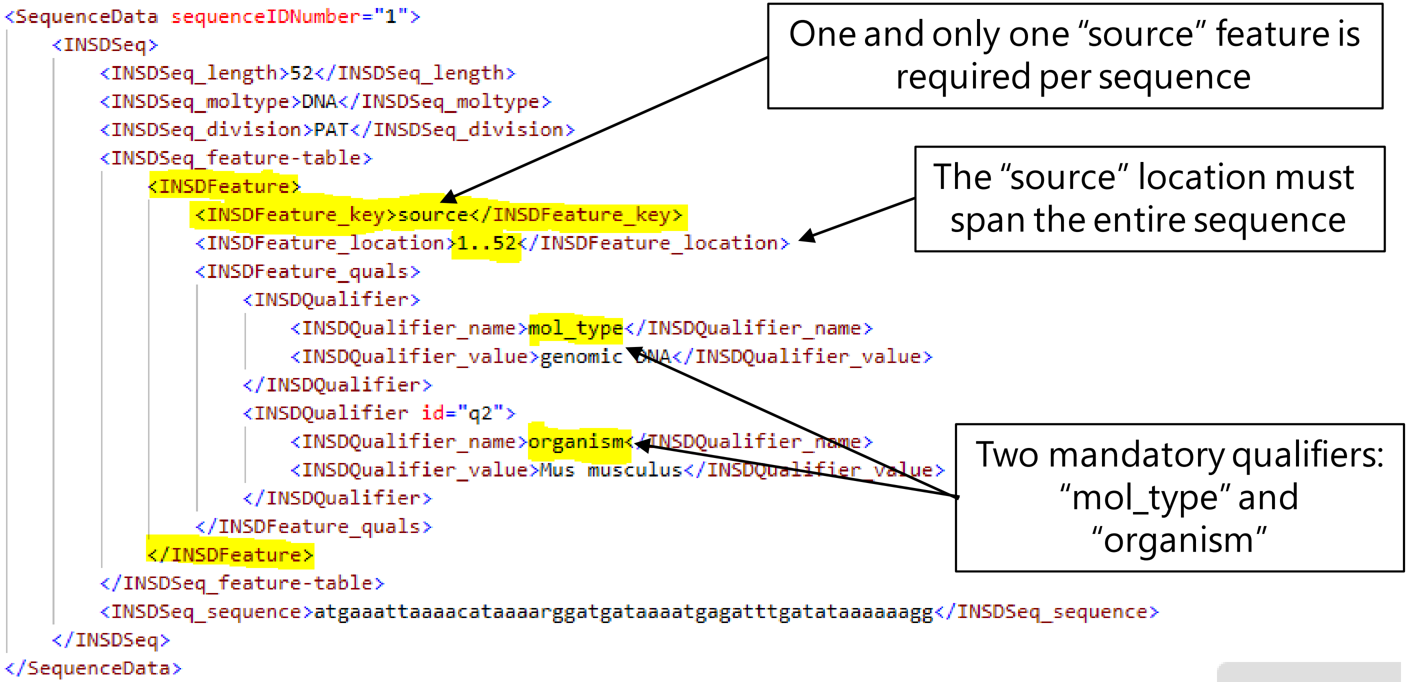
The sequence length

The molecule type (DNA, RNA, or AA)

The division (always “PAT”)

WIPO ST.26: basics
the “sequence data part” (cont.)

The mandatory “source” or “SOURCE” feature



```
<SequenceData sequenceIDNumber="1">
    <INSDSeq>
        <INSDSeq_length>52</INSDSeq_length>
        <INSDSeq_moltype>DNA</INSDSeq_moltype>
        <INSDSeq_division>PAT</INSDSeq_division>
        <INSDSeq_feature-table>
            <INSDFeature>
                <INSDFeature_key>source</INSDFeature_key>
                <INSDFeature_location>1..52</INSDFeature_location>
                <INSDFeature_quals>
                    <INSDQualifier>
                        <INSDQualifier_name>mol_type</INSDQualifier_name>
                        <INSDQualifier_value>genomic DNA</INSDQualifier_value>
                    </INSDQualifier>
                    <INSDQualifier id="q2">
                        <INSDQualifier_name>organism</INSDQualifier_name>
                        <INSDQualifier_value>Mus musculus</INSDQualifier_value>
                    </INSDQualifier>
                </INSDFeature_quals>
            </INSDFeature>
        </INSDSeq_feature-table>
        <INSDSeq_sequence>atgaaattaaaacataaaarggatgataaaatgagatttgatataaaaaagg</INSDSeq_sequence>
    </INSDSeq>
</SequenceData>
```

One and only one “source” feature is required per sequence

The “source” location must span the entire sequence

Two mandatory qualifiers: “mol_type” and “organism”

WIPO ST.26: basics
the “sequence data part” (cont.)

The mandatory “mol_type” and “MOL_TYPE” qualifiers – value choices:

DNA

- genomic DNA
- other DNA
- unassigned DNA

RNA

- genomic RNA
- mRNA
- tRNA
- rRNA
- other RNA
- transcribed RNA
- viral cRNA
- unassigned RNA

AA

- protein

WIPO ST.26: basics
the “sequence data part” (cont.)

The mandatory “organism” and “ORGANISM” qualifiers – value choices:

- Latin genus and species name e.g., “Mus musculus”
- Genus name followed by “sp.” e.g., “Mus sp.”
- Virus name e.g., “Torque teno virus 1”
- “unidentified”
- “synthetic construct”

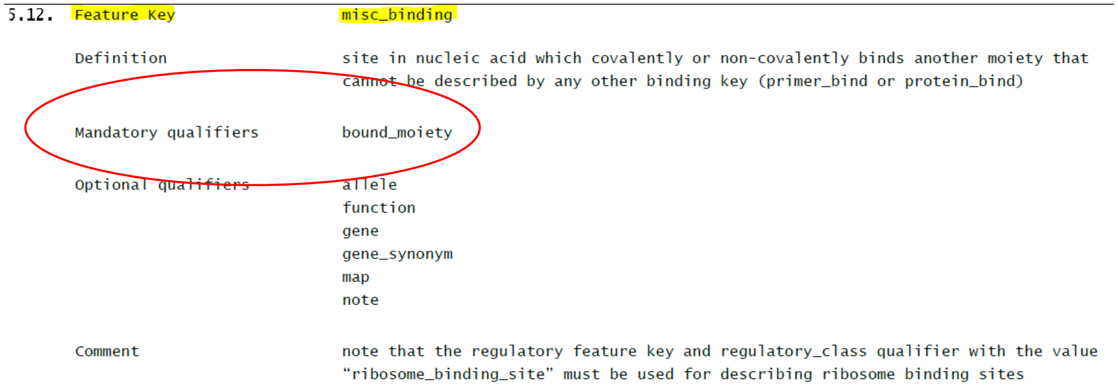
Common names, such as “mouse,” must not be used as the organism name. If desired, common names can be included in the sequence listing in a note qualifier.

WIPO ST.26: basics
the “sequence data part” (cont.)

Feature Keys and Qualifiers *(see WIPO Standard ST.26, Annex I, Sections 5-8)*

In addition to the mandatory “source” or “SOURCE” feature, applicants can add multiple optional features to further describe the sequence.

- Different feature keys for nucleotide sequences and amino acid sequences;
- Each feature may have one or more optional qualifiers, and may have a mandatory qualifier.



5.12.		
	Feature Key	misc_binding
	Definition	site in nucleic acid which covalently or non-covalently binds another moiety that cannot be described by any other binding key (primer_bind or protein_bind)
	Mandatory qualifiers	bound_moiety
	Optional qualifiers	allele function gene gene_synonym map note
	Comment	note that the regulatory feature key and regulatory_class qualifier with the value “ribosome_binding_site” must be used for describing ribosome binding sites

(WIPO ST.26, Annex I, Sections 5-8)

WIPO ST.26: basics
the “sequence data part” (cont.)

The sequence itself:

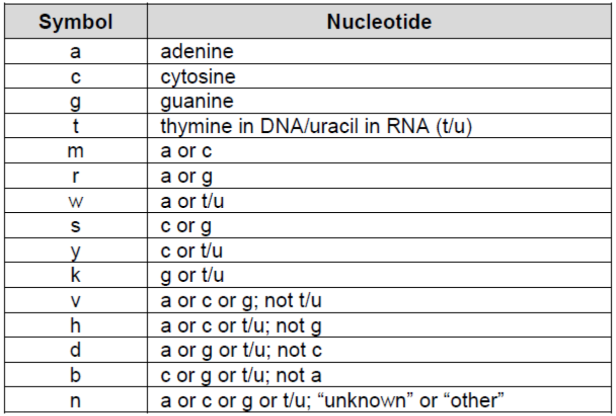
```
<SequenceData sequenceIDNumber="1">
    <INSDSeq>
        <INSDSeq_length>52</INSDSeq_length>
        <INSDSeq_moltype>DNA</INSDSeq_moltype>
        <INSDSeq_division>PAT</INSDSeq_division>
        <INSDSeq_feature-table>
            <INSDFeature>
                <INSDFeature_key>source</INSDFeature_key>
                <INSDFeature_location>1..52</INSDFeature_location>
                <INSDFeature_quals>
                    <INSDQualifier>
                        <INSDQualifier_name>mol_type</INSDQualifier_name>
                        <INSDQualifier_value>genomic DNA</INSDQualifier_value>
                    </INSDQualifier>
                    <INSDQualifier id="q2">
                        <INSDQualifier_name>organism</INSDQualifier_name>
                        <INSDQualifier_value>Mus musculus</INSDQualifier_value>
                    </INSDQualifier>
                </INSDFeature_quals>
            </INSDFeature>
        </INSDSeq_feature-table>
        <INSDSeq_sequence>atgaaattaaaacataaaarggatgataaaatgagatttgatataaaaaagg</INSDSeq_sequence>
    </INSDSeq>
</SequenceData>
```

WIPO ST.26: basics
the “sequence data part”

Nucleotide sequences:

- All lower case symbols;
- No spaces, no numbering;
- No “u” symbols; “t” represents uracil in RNA *(WIPO Standard ST.26, pgh. 14)*
- ”n” has a default value of “any one of ‘a’, ‘c’, ‘g’, or ‘t/u’”.

(WIPO Standard ST.26, pgh. 15)



Symbol	Nucleotide
a	adenine
c	cytosine
g	guanine
t	thymine in DNA/uracil in RNA (t/u)
m	a or c
r	a or g
w	a or t/u
s	c or g
y	c or t/u
k	g or t/u
v	a or c or g; not t/u
h	a or c or t/u; not g
d	a or g or t/u; not c
b	c or g or t/u; not a
n	a or c or g or t/u; “unknown” or “other”

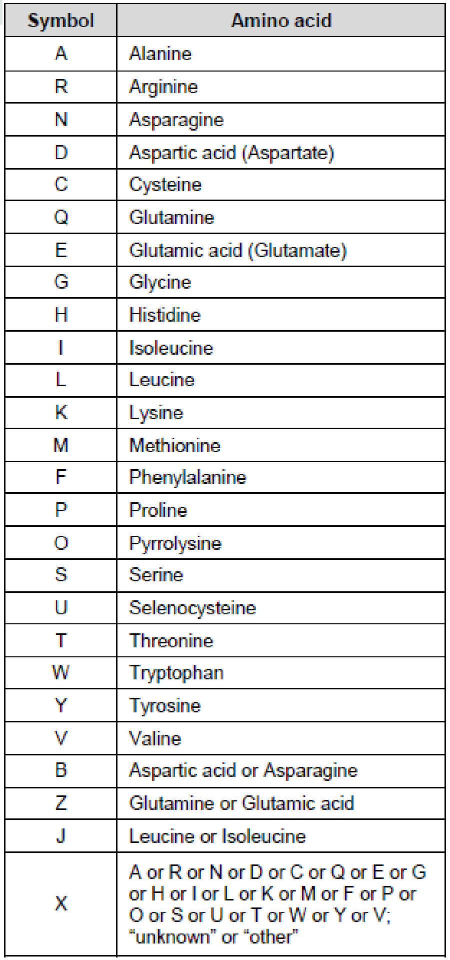
(WIPO Standard ST.26, Annex I, Table 1)

WIPO ST.26: basics the “sequence data part” (cont.)

Amino acid sequences:

- All single letter, upper case symbols;
- No spaces, no numbering;
- ”X” has a default value of “any one of ‘A’, ‘R’, ‘N’, ‘D’, ‘C’, ‘Q’, ‘E’, ‘G’, ‘H’, ‘I’, ‘L’, ‘K’, ‘M’, ‘F’, ‘P’, ‘O’, ‘S’, ‘U’, ‘T’, ‘W’, ‘Y’, or ‘V’”.

(WIPO Standard ST.26, pgh. 15)



Symbol	Amino acid
A	Alanine
R	Arginine
N	Asparagine
D	Aspartic acid (Aspartate)
C	Cysteine
Q	Glutamine
E	Glutamic acid (Glutamate)
G	Glycine
H	Histidine
I	Isoleucine
L	Leucine
K	Lysine
M	Methionine
F	Phenylalanine
P	Proline
O	Pyrrolysine
S	Serine
U	Selenocysteine
T	Threonine
W	Tryptophan
Y	Tyrosine
V	Valine
B	Aspartic acid or Asparagine
Z	Glutamine or Glutamic acid
J	Leucine or Isoleucine
X	A or R or N or D or C or Q or E or G or H or I or L or K or M or F or P or O or S or U or T or W or Y or V; “unknown” or “other”

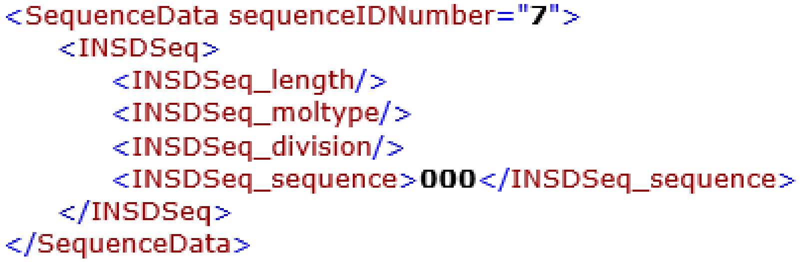
(WIPO Standard ST.26, Annex I, Table 3)

WIPO ST.26: basics
the "sequence data part" (cont.)

Skipped sequences: allow an applicant to delete sequence data from a sequence listing without the need to renumber subsequence sequences.

- INSDSeq_length, INSDSeq_moltype, INSDSeq_division present, but with no value;
- No feature table and no source feature;
- Sequence element must have the value "000".

(WIPO Standard ST.26, pgh. 15)



```
<SequenceData sequenceIDNumber="7">
    <INSDSeq>
        <INSDSeq_length/>
        <INSDSeq_moltype/>
        <INSDSeq_division/>
        <INSDSeq_sequence>000</INSDSeq_sequence>
    </INSDSeq>
</SequenceData>
```

WIPO ST.26: contents

- **Main Body** – Requirements for inclusion/representation.
- **Annex I** – Controlled vocabulary based on INSDC.
- **Annex II** – ST.26 Document Type DTD.
- **Annex III** – example ST.26 Sequence Listing XML file.
- **Annex IV** – Character Subset of Basic Latin Code for ST.26 XML Instance .
- **Annex V** – INDS Data Exchange Requirements (IPOs only).
- **Annex VI** – Guidance Document with Examples.
- **Appendix to Annex VI** –XML file including all of the sequence disclosures exemplified in Annex VI .
- **Annex VII** – Recommendation for the Transformation of a Sequence Listing from ST.25 to ST.26.

WIPO ST.26: main body

Paragraph reference	Content
1-9	Introduction; Definitions; Scope; References
10-37	Representation of sequences
38-49	Structure of the sequence listing in XML
50-71	Sequence data part; Feature table; Feature keys; Mandatory feature keys; Feature location
72-84	Feature qualifiers; Mandatory feature qualifiers
85-100	Free text; Coding sequences; Variants

WIPO ST.26: annex I

controlled vocabulary

Section	Content
1	List of Nucleotides (lower case, single letter symbols)
2	List of Modified Nucleotides
3	List of Amino Acids (upper case, single letter symbols)
4	List of Modified Amino Acids
5	Feature Keys for Nucleotide Sequences
6	Qualifiers for Nucleotide Sequences
7	Feature Keys for Amino Acids (adapted from UniProt)
8	Qualifiers for Amino Acid Sequences
9	Genetic Code Tables

WIPO ST.26: annex II

the ST.26 DTD

- Current version 1.3
- General Information Part
    - Elements related to patent application information.
- Sequence Data Part
    - Subset of the INSDC DTD.
    - One or more sequence data elements where each element contains information about one sequence.

WIPO ST.26: annex VI

the “guidance document”

- Contains 49 real-world examples of sequence disclosures and an explanation of how ST.26 rules apply to each example.

- Each example addresses:
  1. Whether the sequence is required, permitted, or prohibited from inclusion in a sequence listing.
  2. If the sequence is required or permitted to be included in a sequence listing, how must it be represented.

- The Appendix to Annex VI is an ST.26 XML sequence listing that includes all of the examples presented in the Guidance Document.

WIPO ST.26: annex VII

Recommendation for the transformation of a sequence listing from ST.25 to ST.26

- Requirements of ST.26 differ from ST.25 – ST.26 rules requires information that was not required by ST.25 rules.

- Transformation of a sequence listing from ST.25 format to ST.26 format will always require input from the applicant.

- Transformation of a compliant ST.25 sequence listing into ST.26 format will not result in new matter if the recommendations in Annex VII are followed.

- Twenty transformation scenarios presented with recommendations and examples.

WIPO sequence

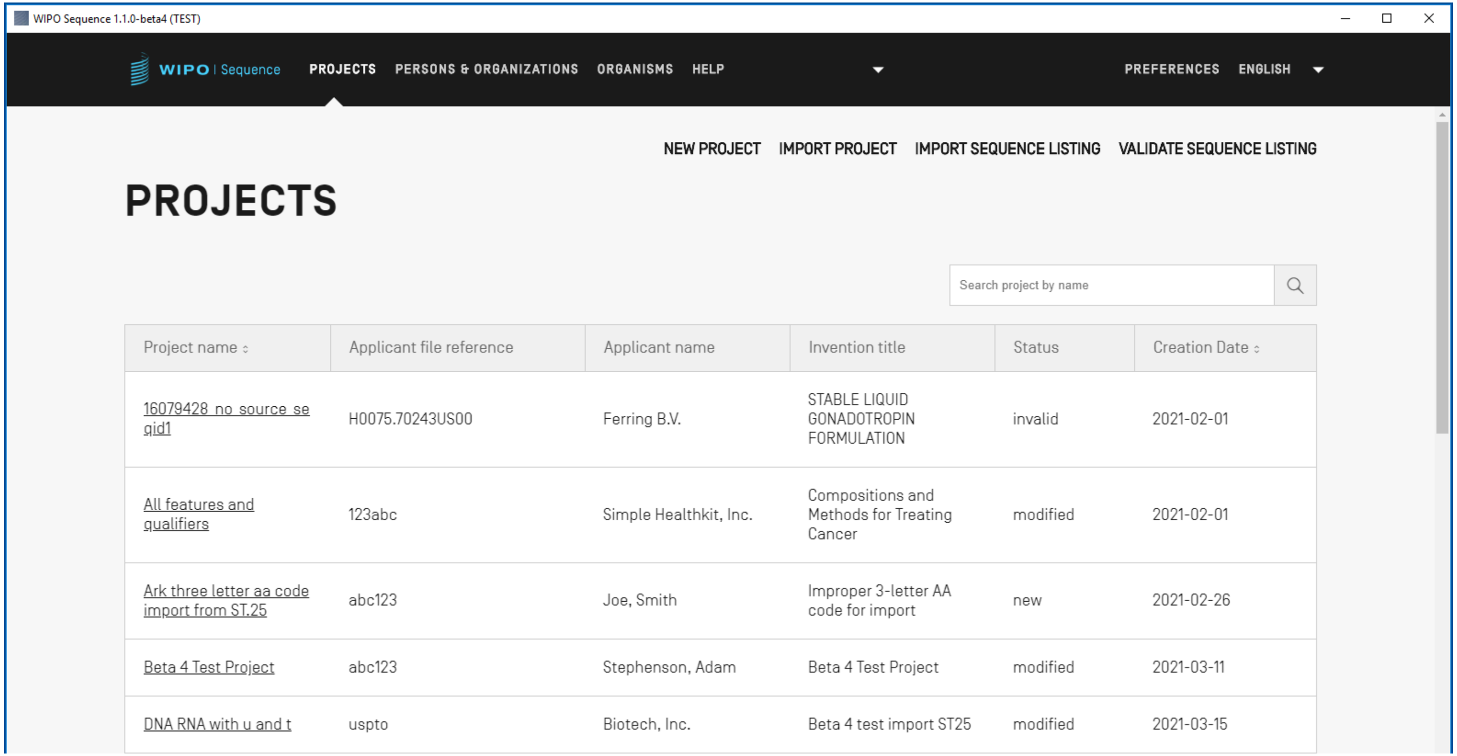
ST.26 authoring and validation tool for applicants

- Desktop tool developed by WIPO to support authoring, validation, and generation of ST.26 compliant sequence listings.
- Member states requested WIPO develop this common tool for all Offices and applicants.
- Use of WIPO Sequence simplifies ST.26 XML creation with a user friendly interface – no need to ever directly edit an XML file.
- Available to download for free from

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

WIPO sequence

main projects page

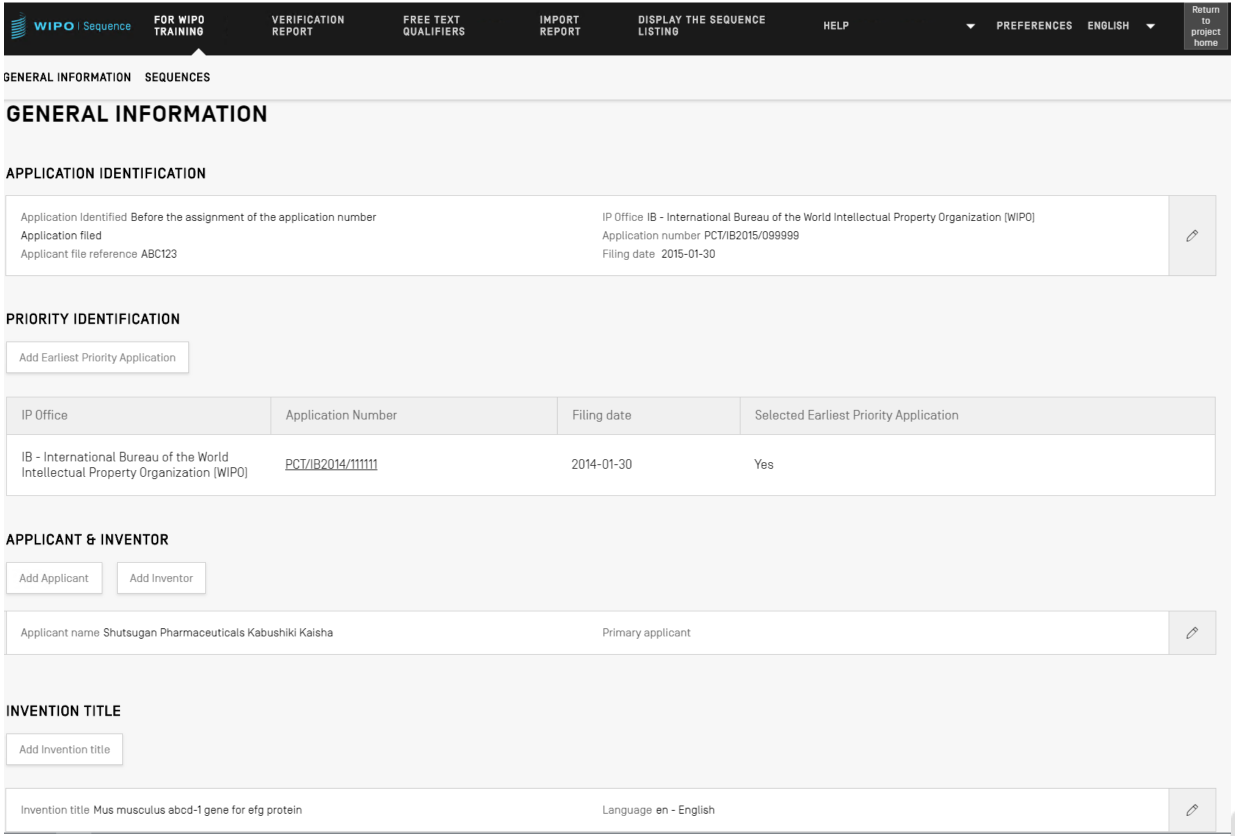


PROJECTS

Project name	Applicant file reference	Applicant name	Invention title	Status	Creation Date
16079428_no_source_seqid1	H0075.70243US00	Ferring B.V.	STABLE LIQUID GONADOTROPIN FORMULATION	invalid	2021-02-01
All features and qualifiers	123abc	Simple Healthkit, Inc.	Compositions and Methods for Treating Cancer	modified	2021-02-01
Ark three letter aa code import from ST.25	abc123	Joe, Smith	Improper 3-letter AA code for import	new	2021-02-26
Beta 4 Test Project	abc123	Stephenson, Adam	Beta 4 Test Project	modified	2021-03-11
DNA RNA with u and t	uspto	Biotech, Inc.	Beta 4 test import ST25	modified	2021-03-15

WIPO sequence

project information view



GENERAL INFORMATION

APPLICATION IDENTIFICATION

Application Identified Before the assignment of the application number
Application filed
Applicant file reference ABC123
IP Office IB - International Bureau of the World Intellectual Property Organization (WIPO)
Application number PCT/IB2015/099999
Filing date 2015-01-30

PRIORITY IDENTIFICATION

IP Office	Application Number	Filing date	Selected Earliest Priority Application
IB - International Bureau of the World Intellectual Property Organization (WIPO)	PCT/IB2014/111111	2014-01-30	Yes

APPLICANT & INVENTOR

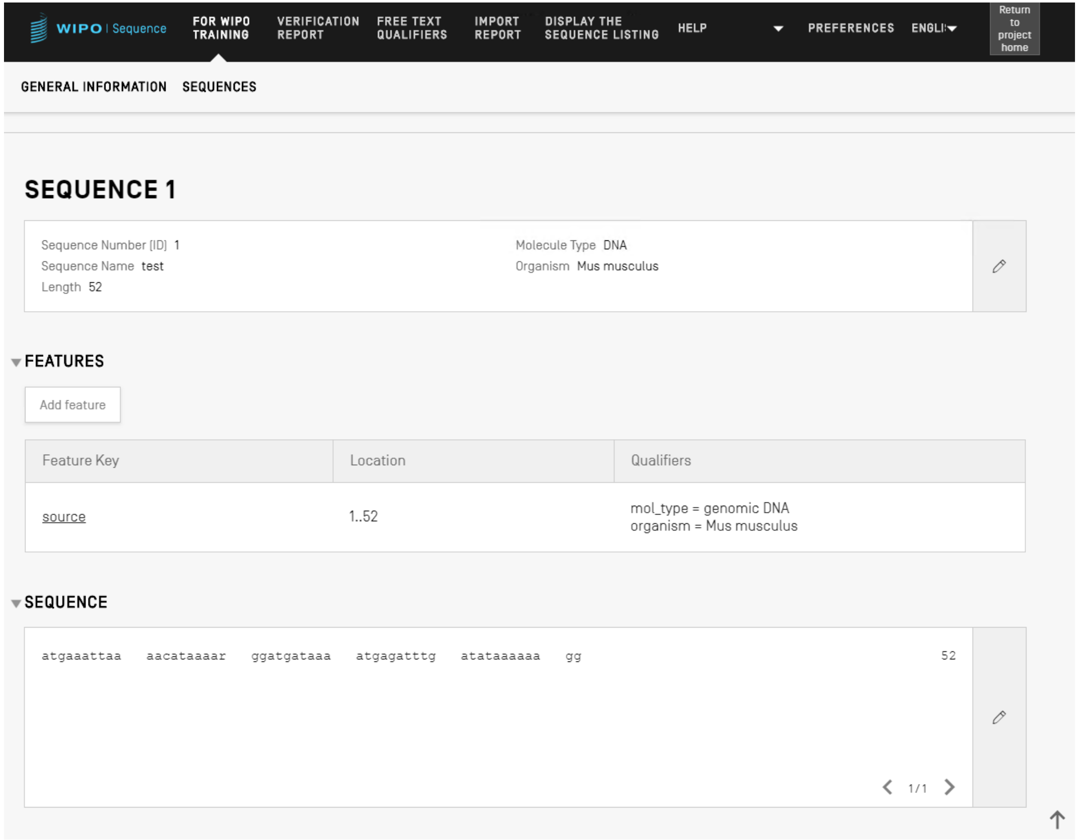
Applicant name Shutsugan Pharmaceuticals Kabushiki Kaisha
Primary applicant

INVENTION TITLE

Invention title Mus musculus abcd-1 gene for efg protein
Language en - English

WIPO sequence

sequence information view



SEQUENCE 1

Sequence Number [ID] 1
Sequence Name test
Length 52

Molecule Type DNA
Organism Mus musculus

FEATURES

Feature Key	Location	Qualifiers
source	1..52	mol_type = genomic DNA organism = Mus musculus

SEQUENCE

```
atgaaattaa   aacataaaar   ggatgataaa   atgagatttg   atataaaaaa   gg                    52
```

WIPO sequence

ST.26 authoring and validation tool for applicants

- Sequence information can be saved in a project, validated, and then a sequence listing in ST.26 format can be generated.
- Data can be imported from: ST.26 sequence listings, ST.26 projects, ST.25 sequence listings, multi-sequence format files, raw format files, and FASTA format files.
- Validation of projects as well as sequence listings in XML format.
- Feature keys, qualifiers, and organism names can be easily selected from drop-down menus.
- Applicant and Inventor information can be stored in a “Persons and Organizations” database.
- Supports export and import of XLIFF files used by translators.

Resources:

- Standard ST.26

https://www.wipo.int/export/sites/www/standards/en/pdf/03-26-01.pdf

- WIPO Sequence tool

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

- Training Sessions from WIPO

https://www.wipo.int/meetings/en/topic.jsp?group_id=330

- WIPO FAQ document

https://www.wipo.int/standards/en/sequence/faq.html

Questions?

Glossary: acronyms

- CWS: Committee on WIPO Standards
- DDBJ: DNA Databank of Japan
- EMBL-EBI: The European Bioinformatics Institute
- EPO: European Patent Office
- INSDC: International Nucleotide Sequence Database Collaboration
- IPO: Intellectual Property Office
- NCBI: National Center for Biotechnology Information
- WIPO: World Intellectual Property Organization

UNITED STATES PATENT AND TRADEMARK OFFICE
DEPARTMENT OF COMMERCE