

Filing Sequence Listings in International and National Stage Applications

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Overview

- Sequence listings (SLs) in International Applications (IAs) under the PCT
- Sequence listings (SLs) in National Stage Applications under 35 U.S.C. §371 (371)
- Transfer requests under 37 CFR §1.821(e)
- Revision of WIPO ST.25 –
 Standard for the Presentation of Nucleotide and Amino Acid Sequence Listings in Patent Applications



An IA Disclosing Sequences MUST contain a Sequence Listing (SL)

SL forming part of the IA

- Sometimes called the "paper copy" or "written form"
- PCT Rule 5.2(a) where an IA contains disclosure of one or more nucleotide and/or amino acid sequences, the description **shall** contain a SL
 - » unbranched nucleotide sequences with 10 or more "specifically defined" nucleotides
 - "> unbranched, non-D amino acid sequences with 4 or more "specifically defined" amino acids

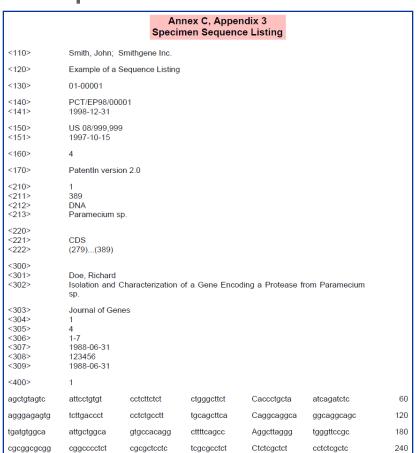
SL not forming part of the IA

- Sometimes called the "CRF," "search tool," or "electronic form"
- PCT Rule 13ter.1(a) the International Searching Authority (ISA) may invite applicant to furnish a SL in electronic form (text format) for search



PCT Rule 5.2(a) - Sequence Listing Shall Comply with PCT Administrative Instructions

SL compliant with PCT AI Annex C VS. Table containing sequence disclosure



- NOT a SL, despite label
- Should be numbered as part of description

C T :		
Sequence Listing	T . D	B: 1 : 16
ID Number	Text Description	Biological Sequence
SEQ ID NO:1	Toxin 1 – Subunit A	ALRDYHPADGRVSYVMTAEDG
		QDYHGSVRWDSSTLGAILMRR
		TDLSVTAEALRGSHSMLDLYRS
		IGVRGITHNKILWDSSTLLAIGA
		ILNCHHASRVAGRSYVMETAED
		NWGGRISFGRVSDQGHYLVSSL
		RVERNVTGFVNRTNNRFRLAEA
		TVEVTFAEDLAILVALILNCHHA
		SVARMAPEEFDSRRMHRNIQN
		NTRNVFGTVYLNNPTGISSYTN
		NRVSFTAKYTDVLSVNRIASTP
		LQTISSGGLLSTDIMDGTGSFRT
SEQ ID NO:2	Toxin 2 – Subunit A	ALRDYHPAGESVSYVMTAEDG
		LDYHGSVRWYRSTLGAILMRR
		TELSVTAEAMRGSSSMLDLYRS
		IGVRGITHNKILWDSSTLLAIGA
		ILNVHDASRVAGRSYVMETAED
		NWGGRISFGRVSHQGHYLVSSL
		SVERNVTGFVNRTNNRFRLAEA
		TVEVTFAEDLAILVALILNCHHA
		SYARMAPEEFDSRRMHRNIQN
		NTRNVFGTVYLNNPTGISSYTN
		NRVSFTAKYTDVLSVNRIASTP
		LQTISSGGLLSTDIMDGTGSFRT



Options for Filing a SL Forming Part of an IA

RECOMMENDED

In text format via EFS-Web on the international filing date (IFD)

- Or on CD the same day where the file is too large for EFS-Web
- Serves both as part of the IA and as the CRF
- No page fees
- No requirement for PDF copy or statement of identity

LESS PREFERRED

In PDF format via EFS-Web on the IFD

- MUST still provide a SL in text format for search with a statement of identity
- FULL page fees no upper limit

LEAST PREFERRED

On paper as part of an IA filed on paper

- MUST still provide a SL in text format for search with a statement of identity
- FULL page fees no upper limit



Options for Filing a SL NOT Forming Part of the IA (CRF)

MUST be in text format

RECOMMENDED

Via EFS-Web (Not required if SL forming part of the IA is in text format)

- Or on CD the same day where the file is too large for EFS-Web
- MUST be filed with a statement of identity where SL forming part of the IA is in paper or PDF format
- MUST be filed with a statement of no new matter when filed after the IFD

LESS PREFERRED

On CD accompanying an IA filed on paper

 MUST be filed with a statement of identity or no new matter, as necessary



Options for Filing a SL-Related Table in an IA

- CANNOT be submitted in text format
 - CANNOT be provided on a CD
- MUST be numbered as part of, and in the same format as, the description
 - In PDF format via EFS-Web as part of a fully electronic IA
 - On paper as part of an IA filed on paper
 - FULL page fees no upper limit



Request – Box IX –PCT SAFE

Parts of the IA

Check list	number of sheets	electronic file(s) attached
Request (including declaration sheets)	6	/
Description	86	_
Claims	10	-
Abstract	1	/
Drawings	24	-
TOTAL	127	
Accompanying Items	paper document(s) attached	electronic file(s) attached
Fee calculation sheet	✓	-
PCT-SAFE physical media	_	/

Accompanying items NOT part of the IA



Request – Box IX – PCT/RO/101

Parts of the IA

Accompanying items NOT part of the IA

Γ						
	Box No. IX CHECK LIST for EFS-Web filings - this	sheet is o	nly to be used when filing an international application with RO/US via	EFS-Web		
	This international application Number contains the following: of sheets	followi	remational application is accompanied by the ng item(s) (mark the applicable check-boxes below icate in right column the number of each item):	Number of items		
	(a) request form PCT/RO/101 (including any declarations	1. 🗆	fee calculation sheet :			
	and supplemental sheets) :	2. 🗆	original separate power of attorney :			
	(b) description (excluding any sequence listing part of the	3. 🗆	original general power of attorney :			
	description, see (f), below) :	4. 🗆	copy of general power of attorney; reference number:			
	(c) claims	5. 🗆	priority document(s) identified in Box No. VI as item(s)			
	(e) drawings (if any)	6. 🗆	Translation of international application into			
	(f) sequence listing part of the description in the form of an	7. 🗆	(language):			
	image file (e.g. PDF) :		microorganism or other biological material :			
	Total number of sheets (including the sequence listing part of the description if filed as an image file) 0	8.	(only where item (f) is marked in the left column) copy of the sequence listing in electronic form (Annex C/ST.25 text file) not forming part of the international application but furnished only for the purposes of international search under Rule 13ter.			
	(g) sequence listing part of the description	9. 🗆	(only where item (f) is marked in the left column)			
	☐ filed in the form of an Annex C/ST.25 text file		a statement confirming that "the information recorded in electronic form submitted under			
	☐ WILL BE filed separately on physical data carrier(s), on the same day and in the form of an Annex C/ST.25 text file		Rule 13ter is identical to the sequence listing as contained in the international application" as filed via EFS-Web:			
		10.	copy of results of earlier search(es) (Rule 12bis.1(a)) :			
	Indicate type and number of physical data carrier(s)	11. 🗆	other (specify):			

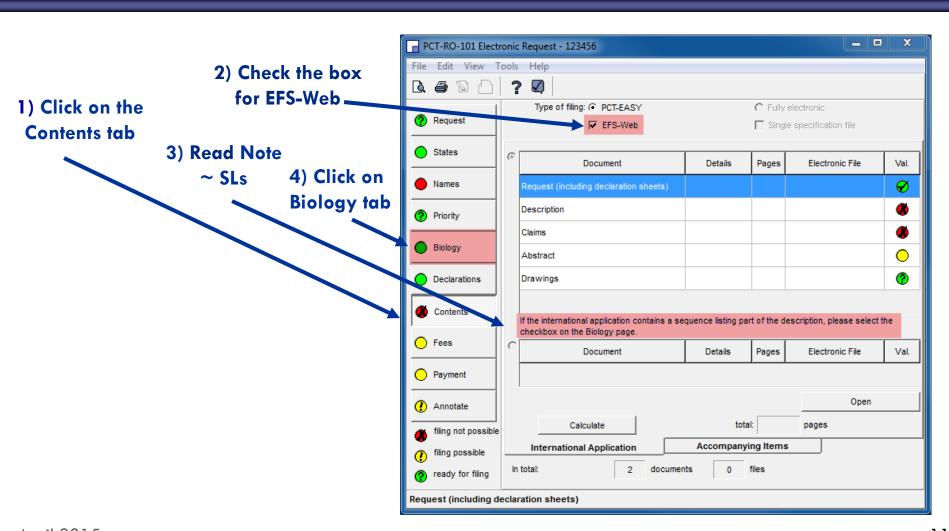


Request MUST Indicate That SL Forms Part of IA

- Incorporation by reference (as in a regular U.S. application) is NOT sufficient
 - If present, some national/regional Offices may require removal
- Failure to identify the SL as part of the IA in the Request
 - May result in a fatally-defective National Stage application
 -)) Where sequences are not otherwise disclosed in the IA
 - >> Even if the SL was provided on the international filing date (IFD)
- Instructions for proper completion of the Request are
 - available on the International Patent Legal Administration home page at www.uspto.gov/go/pct
 PCT & Sequence Listing (SL)
 - July 2009 Administrative Instruction Changes
 - Instructions & Examples of Filled-out Request with SL
 - Conventional Request (PCT/RO/101)
 - PCT-SAFE/EASY

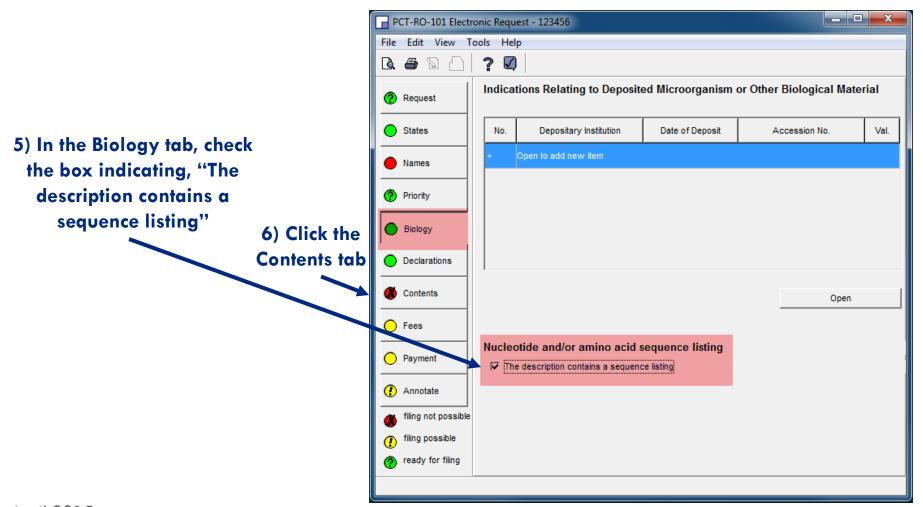


PCT-SAFE Request — Contents Tab Steps 1-4 for Indicating SL as Part of the IA



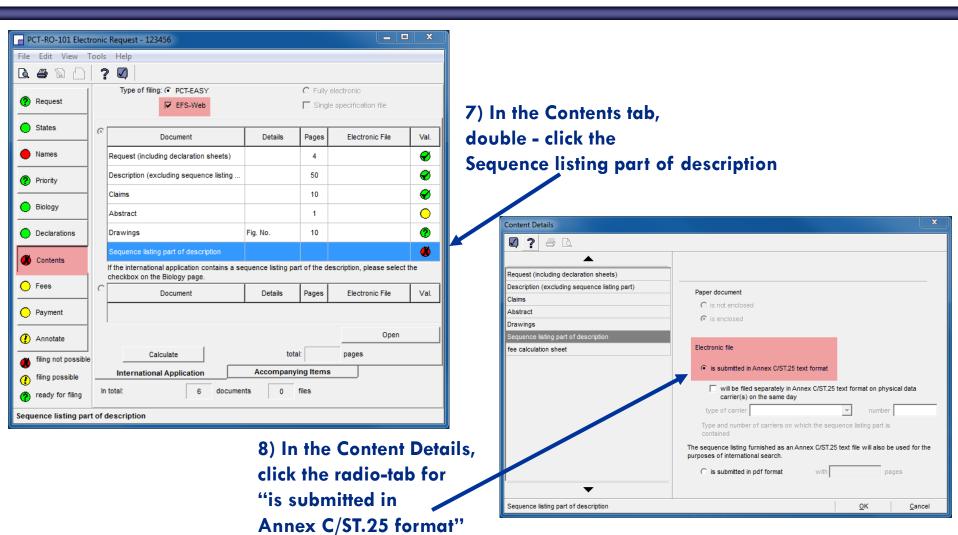


PCT-SAFE Request — Biology Tab Steps 5-6 for Indicating SL as Part of the IA





PCT-SAFE Request — Contents Tab Steps 7-8 for Indicating SL as Part of the IA





PCT-SAFE Request — Checklist EFS-Web SL in Text Format Only

Tables, if	IX	Check list	Number of sheets	Electronic file(s) attached
any, _	IX-1	Request (including declaration sheets)	4	✓
included in	IX-2	Description	50	-
description	IX-3	Claims	10	-
acscription	IX-4	Abstract	1	√
	IX-5	Drawings	10	-
	1X-6a	Sequence listing part of the description (also to be used for the purposes of international search)	-	
	IX-7	TOTAL	75	
		Accompanying Items	Paper document(s) attached	Electronic file(s) attached
	IX-8	Fee calculation sheet	1	-

SL does not appear as an Accompanying item in this scenario

No 13ter statement needed – only ONE SL file

SL text format
forming part of the IA,
no pages indicated,
check for electronic file only



PCT/RO/101 Checklist EFS-Web SL in Text Format Only

	Box No. IX CHECK LIST for EFS-Web filing	gs - this	sheet is only to be used when filing an international application with RO/US v	ia EFS-Web
	11	mber 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
Tables, if	(a) request form PCT/RO/101 (including any declarations and supplemental sheets):	4	☐ fee calculation sheet	Be sure to use the correct sheet
any,	(b) description (excluding any sequence listing part of the description, see (f), below) :	50	original general power of attorney	for EFS-Web
description	(c) claims	10	number:	
	(e) drawings (if any) :	10	6. Translation of international application into (language):	
	(f) sequence listing part of the description in the form of an image file (e.g. PDF) :		7. separate indications concerning deposited microorganism or other biological material	
SL forming part of the IA text format only	Total number of sheets (including the sequence listing part of the description if filed as an image file)	75	8. — fonly where item (f) is marked in the left column) copy of the sequence listing in electronic form (Annex C/ST.25 text file) not forming part of the international application but furnished only for the purposes of international search under Park Inter.	Boxes 8 and 9 not checked
→ ((g) sequence listing part of the description X filed in the form of an Annex C/ST.25 file WILL BE filed separately on physical description		9. only where item (f) is marked in the left column) a statement confirming that "the information recorded in electronic form submitted under Rule 13ter is identical to the sequence listing as contained in the international application"	
(Rarely used - SL > EFS-Web)	carrier(s), on the same day and in the fo of an Annex C/ST.25 text file Indicate type and number of physical data	orm	as filed via EFS-Web: : : : : : : : : : : : : : : : : : :	
April 2015	carrier(s)		11. ☐ other (specify):	1



ISA Invitation to Furnish a Sequence Listing PCT/ISA/225

PCT/ISA/225 is issued when

- Sequences are disclosed, but no SL in text format
- Text SL does not comply with ST.25/PCT Al Annex C
 - » E.g., incorrect entry in <213> field
 - » E.g., insufficient explanation in <223> field
 - » E.g., extraneous text or blank lines
- NO statement of identity or statement of no new matter, if applicable

SL filed in response to PCT/ISA/225 is NOT considered part of IA

- For national/regional stage, IA MUST be amended to include SL as part of the IA
 - » By amendment under PCT Article 34 during Chapter II examination
 - » By a preliminary amendment in National/Regional Stage



If USPTO is NOT Chosen as ISA

- DO NOT file corrected/subsequent SL in EFS-Web
 - Even where CRFD (Computer Readable Form Defective) is visible in Image File Wrapper (IFW)
 - » Automated review of all SLs in text format uploaded to EFS-Web produces a CRFE (Computer Readable Form Entered) or CRFD
 - » RO/US will not issue a PCT/ISA/225
 - File SL directly with chosen ISA
 - » may prevent ISA late fees
 - RO/US will NOT forward to chosen ISA



SL filed after the International Filing Date (IFD)

- A SL filed after the IFD, but during Chapter I, is NOT considered part of IA
 - E.g., in response to a PCT/ISA/225
 - Narrow exception PCT Rule 20.6 incorporation by reference
- A SL filed during Chapter II may be considered part of the IA
- Determination is made as to whether SL contains new matter
 - By the International Preliminary Examining Authority (IPEA)
 - » Where SL provided as an amendment under PCT Article 34
 - By the Designated/Elected Office (DO/EO)
 - » The decision of the IPEA is not binding on any DO/EO
 - » The SL may be considered to contain new matter by a national/regional Office even if an IPEA did not object



Publication of SLs in IAs

- SLs forming part of the IA
 - Published on PATENTSCOPE
 - » Under "Published International Application"
 - » As a line item separate from remainder of published IA http://patentscope.wipo.int/search/en/search.jsf
- SLs not forming part of the IA
 - Made available on PATENTSCOPE
 - » Under "Related Documents on file at the International Bureau"
- Review PATENTSCOPE to verify proper treatment of the SL



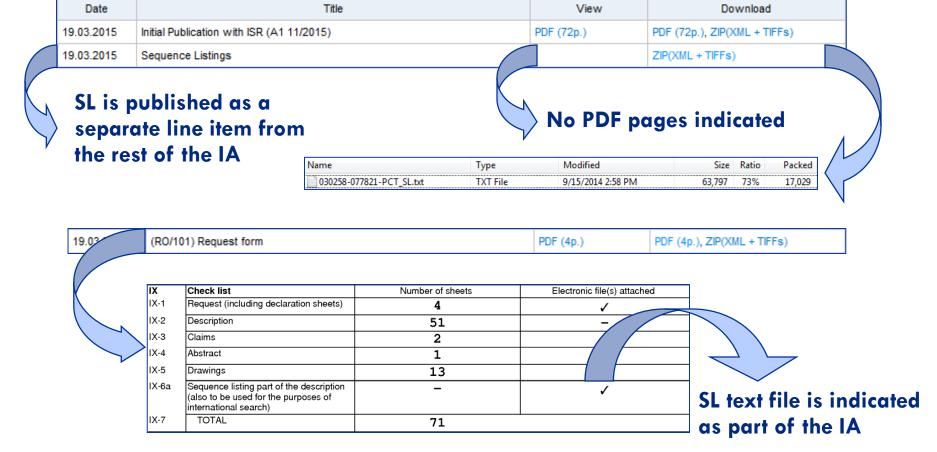
PATENTSCOPE

http://patentscope.wipo.int/search/en/search.jsf





Published International Application (IA) with SL in Text Format



Published International Application

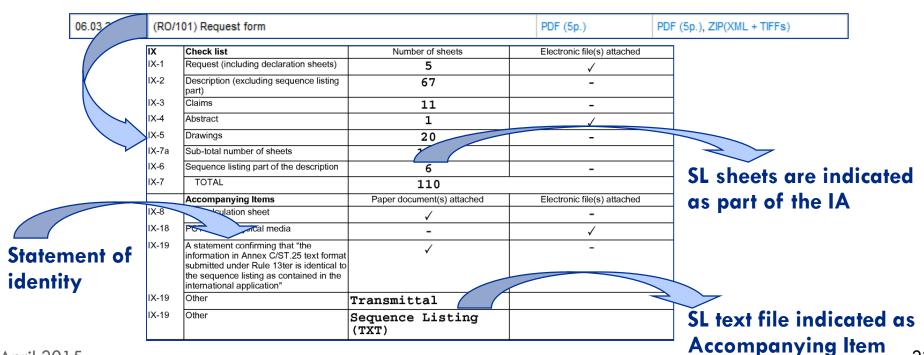


Published International Application (IA) with SL in PDF Format

Published International Application						
Date	Title	View	Download			
06.03.2014	Initial Publication with ISR (A1 10/2014)	PDF (101p.)	PDF (101p.), ZIP(XML + TIFFs)			
06.03.2014	Sequence Listings	PDF (6p.)	PDF (6p.), ZIP(XML + TIFFs)			

SL is published as a line item separate from the rest of the IA

Number of pages of SL in PDF is indicated



April 2015

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SLs Provided by ISA to IB Available on PATENTSCOPE

SL is published under "Related Documents"

SL is indicated as "only for the purposes of international search (Rule 13ter)"

Statement of identity

No PDF pages of SL ZIP file only

	Related Documents on file at the Internat	ional Bureau	
Date	Title	View	Download
19.03.2015	Replacement, Substitute sheets (Rule 26)	PDF (26p.)	PDF (26p.), ZIP(XML + TIFFs)
19.03.2015	(RO/102) Notification Concerning Payment of Prescribed Fees	PDF (2p.)	PDF (2p.), ZIP(XML + TIFFs)
19.03.2015	(ISA/202) Notification of Receipt of Search Copy	PDF (1p.)	PDF (1p.), ZIP(XML + TIFFs)
19.03.2015	(RO/105) Notification of the International Application Number and of the International Filing Date	PDF (1p.)	PDF (1p.), ZIP(XML + TIFFs)
19.03.2015	US 61/877,557 13.09.2013 (Pr. Doc.)	PDF (90p.)	PDF (90p.), ZIP(XML + TIFFs)
19.03.2015	Application Body as Filed	PDF (86p.)	PDF (86p.), ZIP(XML + TIFFs)
19.03.2015	Sequence listing only for the purposes of international search (Rule 13ter)	PDF (0p.)	PDF (0p.), ZIP(XML + TIFFs)
19.03.2015	(RO/101) Request form	<u>PDF (</u> 5p.)	PDF (5p.), ZIP(XML + TIFFs)
19,03.2015	(IB/304) Notification Concerning Submission or International Priority Document	PDF (1p.)	PDF (1p.), ZIP(XML + TIFFs)
19.03.2015	(RO/106) Invitation to Correct Defects in the International Application	PDF (2p.)	PDF (2p.), ZIP(XML + TIFFs)
19.00	Cover Letter	PDF (2p.)	PDF (2p.), ZIP(XML + TIFFs)
19.03.2015	tte r	PDF (2p.)	PDF (2p.), ZIP(XML + TIFFs)
19.03.2015	Statement relative to Seq List only for the purposes of international search (Rule 13ter)	PDF (2p.)	PDF (2p.), ZIP(XML + TIFFs)
19.03.2015	(ISA/206) Invitation to Pay Additional Fees and, Where Applicable, Protest Fee	PDF (3p.)	PDF (3p.), ZIP(XML + TIFFs)
19.03.2015	(IB/311) Notification Concerning Availability of Publication of the International Application	PDF (1p.)	PDF (1p.), ZIP(XML + TIFFs)
19.03.2015	(IB/301) Notification of receipt of record copy	PDF (1p.)	PDF (1p.), ZIP(XML + TIFFs)



SLs in National Stage Applications filed under 35 U.S.C. 371

A SL as part of the application

- 37 CFR §1.821(c) a patent application disclosing nucleotide and/or amino sequences must contain a SL
 - » unbranched nucleotide sequences with 10 or more "specifically defined" nucleotides
 - "> unbranched, non-D amino acid sequences, with 4 or more "specifically defined" amino acids

A SL in computer readable form (CRF)

 37 CFR §1.821(e) - a copy of SL part of the application must also be submitted in computer readable form (CRF)

The IA shall be communicated to each designated Office (DO)

- PCT Article 20
- Should include any SL that forms part of the IA
- A SL in electronic form that does not form part of the IA (CRF) is not communicated by the IB to the DO



National Stage Application Contents

- A national stage application ("371") continues the prosecution of the IA
 - Contents of the IA determines contents of the 371
- Simply filing a SL on the date of first submission of the 371
 DOES NOT make it part of the application
 - Unless the SL was already part of the IA
 - » If filed, should be accompanied by a letter explaining its status, e.g. "The sequence listing submitted herewith is identical to the sequence listing forming part of the international application."
 - A SL that was not part of the IA MUST be accompanied by a preliminary amendment to enter it into the 371
 - » E.g., SL in text format submitted to the ISA/US in response to PCT/ISA/225

» See slide 28



National Stage Entry for an IA Having a SL in Text Format as Part of the IA

- SL in text format retrieved from the IB ONLY where Request indicates SL as part of the IA and SL published as part of the IA
 - No need to file SL upon National Stage entry
 - » If filed nonetheless, MUST include a statement of identity to the SL forming part of the IA
 - If SL is not part of the IA, preliminary amendment required (see slide 28)
 - SL in text format not subject to page fees
 - Text format manually uploaded into SCORE
 - » Bibliographic data updated (see slide 40)

SL is published as part of the IA

April 2015

X	Check list	Number of sheets	Electronic file(s) attached	1
IX-1	Request (including declaration sheets)	4	/	
X-2	Description	51	-//	
IX-3	Claims	2		
IX-4	Abstract	1		
IX-5	Drawings	13		
X-6a	Sequence listing part of the description (also to be used for the purposes of international search)	_	√	SL is indicated
IX-7	TOTAL	71		as part of the

	Published International Application						
	Date	Title	View	Download			
	19.03.2015 Initial Publication with ISR (A1 11/2015)		PDF (72p.)	PDF (72p.), ZIP(XML + TIFFs)			
_	19.03.2015	Sequence Listings		ZIP(XML + TIFFs)			

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National Stage Entry for an IA Having a SL in PDF Format as *Part of the IA*

- USPTO retrieves the SL in PDF format from the IB ONLY where it was part of the IA and was published as part of the IA
 - MUST still provide SL in text format NOT retrieved from IB
 - » Together with a statement of identity
 - SL in PDF format subject to page fees
 - Uploaded into IFW

IX	Check list	Number of sheets	Electronic file(s) attached	
IX-1	Request (including declaration sheets)	5	/	
IX-2	Description (excluding sequence listing part)	67		CILI
IX-3	Claims	11	-	→ SL sheets are
IX-4	Abstract	1	√	7
IX-5	Drawings	20	-	⊢ indicated as
IX-7a	Sub-total number of sheets	1/		
IX-6	Sequence listing part of the description	6	-	part of the IA
IX-7	TOTAL	110		
	Accompanying Items	Paper document(s) attached	Electronic file(s) attached	
IX-8	Fee calculation sheet	✓	-	
IX-18	PCT-SAFE physical media	-	1	SL text file
IX-19	A statement confirming that "the information in Annex C/ST.25 text formal submitted under Rule 13ter is identical to the sequence listing as contained in the international application"		-	indicated only as
IX-19	Other	Transmittal		Accompanying
IX-19	Other	Sequence Listing (TXT)		ltem

SL sheets are published as part of the IA

Published International Application					
Date	Title	View	Download		
06.03.2014 Initial Publication with ISR (A1 10/2014)		PDF (101p.)	PDF (101p.), ZIP(XML + TIFFs)		
06.03.2014	Sequence Listings	PDF (6p.)	PDF (6p.), ZIP(XML + TIFFs)		



National Stage Entry for an IA NOT Having a SL Part of the IA

- Submit a SL in text format ONLY via EFS-Web upon 371 entry
 - Excluded when determining the application size fee
 - Serves both as part of the application and as the CRF
 - MUST file a preliminary amendment, together with
 - » A statement that SL in text format does not introduce new matter to IA as of its IFD
 - » An indication of support for the amendment in the 371 application
 - » An incorporation by reference
 - A separate paragraph added to the SPEC that identifies
 - the name of the file
 - the date of creation
 - size of the file in bytes
 - As specified in the Legal Framework for EFS-Web

http://www.uspto.gov/patents/process/file/efs/guidance/New legal framework.jsp



Revision of Patent Term Adjustment Provisions

Patent term adjustment will be reduced

- If an application is not in condition for examination within 8 months of
 - » Its filing date
 - » Date of commencement of national stage
- "In condition for examination" includes
 - » A sequence listing in compliance with 37 CFR 1.821-1.825
 - » See 37 CFR 1.704(f)
- Effective date December 18, 2013
 - » http://www.gpo.gov/fdsys/pkg/FR-2013-10-21/pdf/2013-24471.pdf



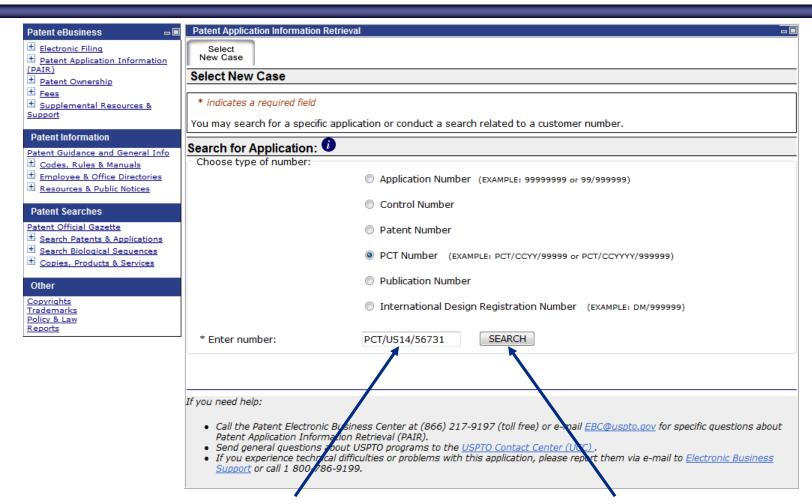
SL Text File to be Submitted upon National Stage Entry

- From applicant's records, whenever available
- From Private or Public PAIR
 - If the SL text file was provided April 2007 or later
 - Retrieved via the Supplemental Content Tab
 - » See slides 31-34
- From PATENTSCOPE (IB website)
 - Where a SL text file was provided
 - » As part of the IA
 - » For the purposes of search only under Rule 13ter (CRF) to the ISA
 - » See slides 35-39
- USPTO will update the SL text file

- See slide 40



Downloading SL Text File From PAIR (1)

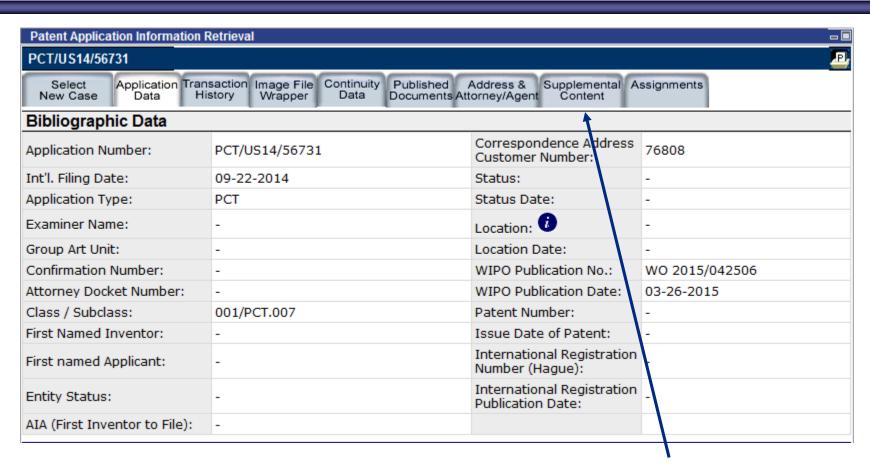


Enter application number

Click "SEARCH"



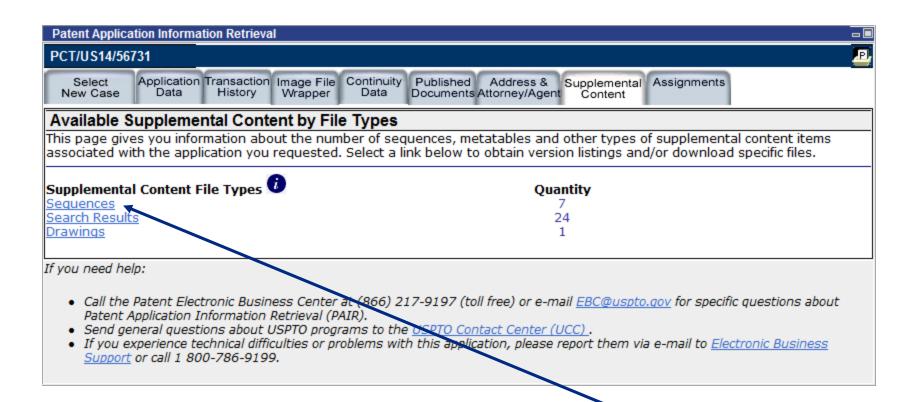
Downloading SL Text File From PAIR (2)



Click "Supplemental Content"



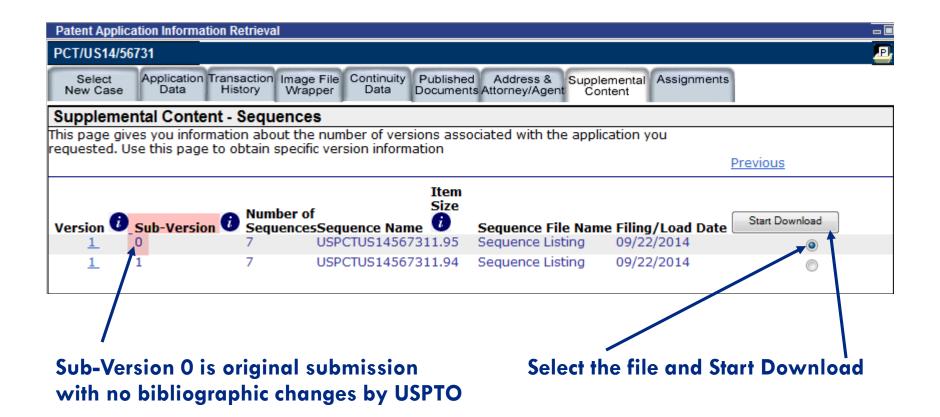
Downloading SL Text File From PAIR (3)



Click "Sequences"



Downloading SL Text File From PAIR (4)





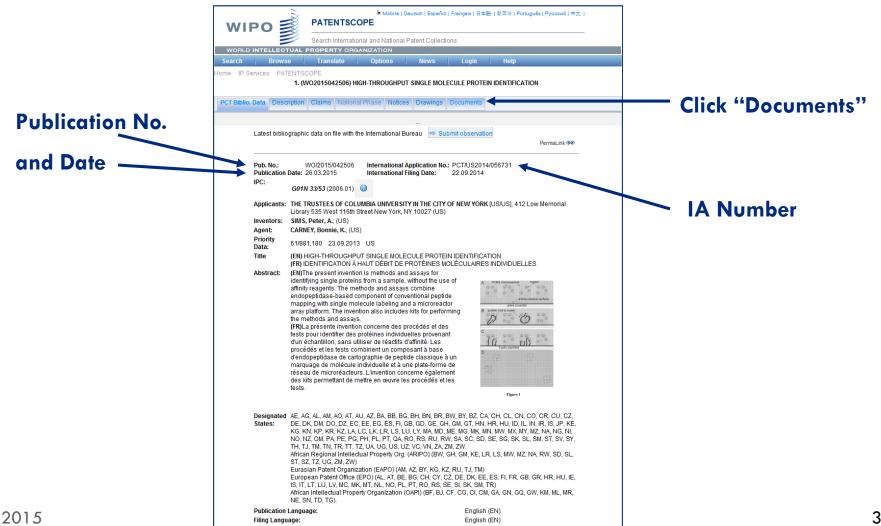
Downloading From PATENTSCOPE (1)

Go to: http://patentscope.wipo.int/search/en/search.jsf



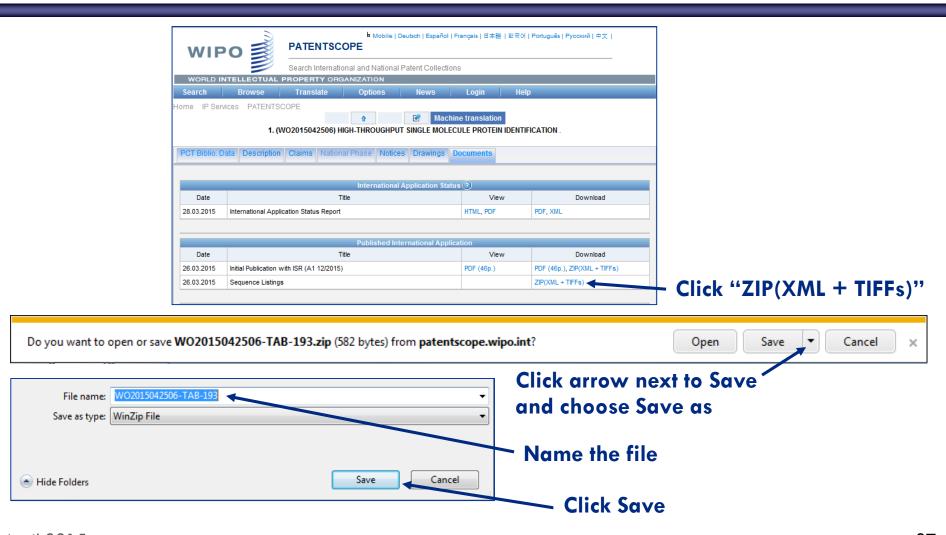


Downloading From PATENTSCOPE (2)



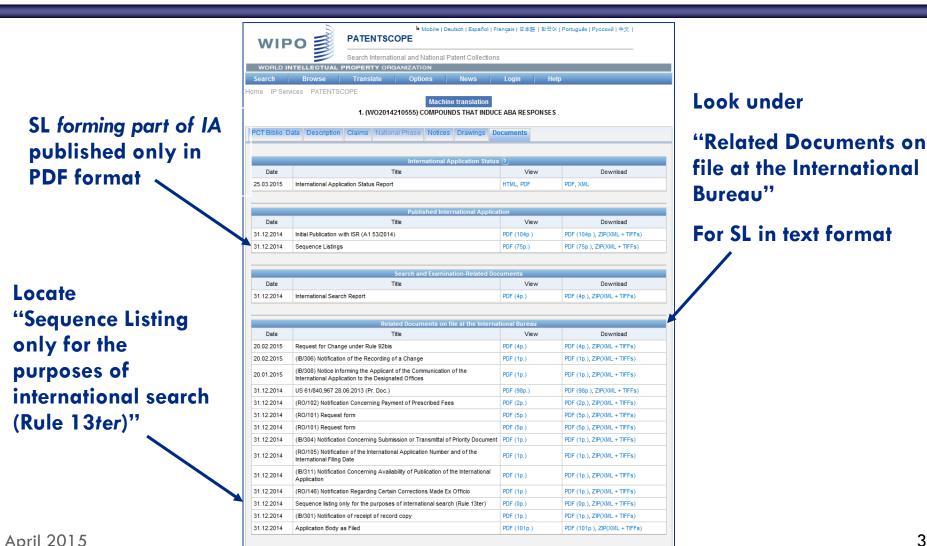


Downloading From PATENTSCOPE SL Text File Forms Part of IA





Downloading From PATENTSCOPE SL Text File is a Search Tool Only (1)





Downloading From PATENTSCOPE SL Text File is a Search Tool Only (2)

Related Documents on file at the International Bureau					
Date	Title	View	Download		
20.02.2015	Request for Change under Rule 92bis	PDF (4p.)	PDF (4p.), ZIP(XML + TIFFs)		
20.02.2015	(IB/306) Notification of the Recording of a Change	PDF (1p.)	PDF (1p.), ZIP(XML + TIFFs)		
20.01.2015	(IB/308) Notice Informing the Applicant of the Communication of the International Application to the Designated Offices	PDF (1p.)	PDF (1p.), ZIP(XML + TIFFs)		
31.12.2014	US 61/840,967 28.06.2013 (Pr. Doc.)	PDF (98p.)	PDF (98p.), ZIP(XML + TIFFs)		
31.12.2014	(RO/102) Notification Concerning Payment of Prescribed Fees	PDF (2p.)	PDF (2p.), ZIP(XML + TIFFs)		
31.12.2014	(RO/101) Request form	PDF (5p.)	PDF (5p.), ZIP(XML + TIFFs)		
31.12.2014	(RO/101) Request form	PDF (5p.)	PDF (5p.), ZIP(XML + TIFFs)		
31.12.2014	(IB/304) Notification Concerning Submission or Transmittal of Priority Document	PDF (1p.)	PDF (1p.), ZIP(XML + TIFFs)		
31.12.2014	(RO/105) Notification of the International Application Number and of the International Filing Date	PDF (1p.)	PDF (1p.), ZIP(XML + TIFFs)		
31.12.2014	(IB/311) Notification Concerning Availability of Publication of the International Application	PDF (1p.)	PDF (1p.), ZIP(XML + TIFFs)		
31.12.2014	(RO/146) Notification Regarding Certain Corrections Made Ex Officio	PDF (1p.)	PDF (1p.), ZIP(XML + TIFFs)		
31.12.2014	Sequence listing only for the purposes of international search (Rule 13ter)	PDF (0p.)	PDF (0p.), ZIP(XML + TIFFs)		
31.12.2014	(IB/301) Notification of receipt of record copy	PDF (1p.)	PDF (1p.), ZIP(XML + TIFFs)		
31.12.2014	Application Body as Filed	PDF (101p.)	PDF (101p.), ZIP(XML + TIFFs)		

Click "ZIP(XML + TIFFs)" > and save as described

April 2015



Submitting a SL Text File in a U.S. National Stage Application

- Upon national stage entry
 - The IA number may not be in the SL, and
 - The 371 application number may not be known
- The USPTO will update the SL as needed, e.g., to insert
 - The 371 application number
 - The 371(c) date
 - The IA number and IFD

```
SEQUENCE LISTING
<110> Georgia Tech Research Corporation
      Williams, Loren D
      Hsiao, Chiaolong
      Fang, Po-Yu
      Williams, Justin
<120> TARGETING NON-CODING RNA FOR RNA INTERFERENCE
<130> GTRC 6432 PCT
<160> 4
<170> PatentIn version 3.5
<210> 1
<211> 712
<212> RNA
<213> Artificial Sequence
<220>
<223> non-coding interfering RNA
```



Editing a SL Text File

Best Practice

- Open "Project File" from Patentln or other software
 - » Save as a new project

If original file is not available

- Open in a text editor that produces files ONLY in ASCII format
 - » Such as NotePad or an equivalent software
- NOT recommended to use word processing software that produces files in ASCII as well as non-ASCII formats
 - » Such as WORD, WordPad, or Word Perfect



Transfer Requests under 37 CFR 1.821(e)

- Introduced with sequence rules that became effective in 1990
 - For use when the original CRF was not available to the filer
- 37 CFR §1.821(e) provides for "transfer" of a compliant CRF
 - From another application on file in the Office to a new application
 - Where the CRF of the new application is to be identical
 - The other application and the CRF must be completely identified
 - Applicant must state that the CRF from the other application is identical to the paper (or PDF equivalent) or CD copy (under 37 CFR §1.52(e)) of the SL contained in the new application
 - » i.e., the new application must itself contain a SL that forms part of the application



SL Text Format Submission Preferred over Transfer Request

- SL in text format can be easily retrieved from
 - Applicant's records
 - Private or Public PAIR via Supplemental Content Tab
 - From PATENTSCOPE (WIPO website) for an IA
- Transfer Request has numerous disadvantages
 - A SL in PDF or paper MUST be part of the new application
 - » Where SL not part of IA, amendment required to include in 371
 -)) Included in application size fee
 - » Statement of identity required
 - Other application and CRF must be completely identified
 - Often introduces delay when requirements are not met



SL Transfer Request Problems

- Transfer often requested in an application having NO PDF or paper SL part of the application
 - Response to defective transfer request must include
 - » A new transfer request, a PDF or paper SL, as well as an amendment entering the SL into the application
- CRF to be transferred is not adequately identified
 - Application number, filing date, and submission date of CRF required
- No compliant CRF on file in the Office
- No statement that CRF to be transferred is identical to PDF or paper SL part of application



Transfer Request Form

- RECOMMENDATION
 - If transfer must be requested"> Use PTO/SB/93
 - Revised November 2014
 - Contains necessary statements
 - Easy to understand/complete
 - Reduces errors

http://www.uspto.gov/sites/default/files/forms/sb0093.pdf

REQUEST FOR TRANSFER OF A COMPUTER READABLE FORM UNDER 37 CFR 1.821(e)						
Application No.:		First Named Inventor:				
Filing Date:		Practitioner Docket No.:				
Title of the Invention	:					
accordance with as a as a for the above ide only ast othe in application nu	37 CFR 1.821(c), file art of the originally-fil separate amendmer herewith; on computer readable filed computer readable r computer readable mber eadable form was cor	ed specification of this applicat at of the specification filed: ; identical to the sequence infor	mation in the	 ereby requests that it be		
The above refer	enced paper copy or	PDF file of the Sequence Listin	g contains no new	v matter.		
and (b) (i.e., is a 1.821(c) and the via EFS-Web, th readable "Seque	compliant sequence CRF required by 37 e U.S. Patent and Tr ence Listing" that is al	via EFS-Web that complies wit listing ASCII text file), serves a CFR 1.821(e). If a user submit ademark Office will not carry o ready on file for another applic le application as originally filed	s both the paper of s a compliant sequ t a request to use ation pursuant to 3	copy required by 37 CFR uence listing ASCII text file a compliant computer		
	Office will update the	r of a copy of the computer rea copy of the computer readable				
			Date			
Signature						
Name (Print/Typed)				ion Number		
	wet he sisped in second	dance with 37 CFR 1.33. See 37 CF	R 14(d) for signatur	e requirements and certification		
	nust be signed in accord is if more than one signatu			e requiremento una occanoación		

This obsection of minimation is required by 30 50.5.2 and 37 CPT 1,055.5. The influence in Equipment of the Confidentiality is governed by 35 U.S.C. 122 and 37 U.S.C. 122 and



Example of a PROPER Transfer Request

- An IA was filed with the RO/US and includes
 - A SL in PDF format as part of the IA

AND

- A compliant CRF
- The IA enters national stage under 35 U.S.C. §371
 - The SL forming part of the IA in PDF format is in IFW for the 371
 - >>> From the IB
 - Transfer of the compliant CRF from the IA into the 371 is requested
 - » The IA and CRF are completely identified
 - » A statement is provided that the CRF from the IA is identical to the SL in PDF format forming part of the 371



Example 1 of an IMPROPER Transfer Request

- An IA was filed with the RO/US
 - NO SL provided as part of the IA
 - A compliant CRF was provided to ISA/KR in response to a PCT/ISA/225
- The IA enters national stage under 35 U.S.C. §371
 - Transfer of the compliant CRF from the IA into the 371 is requested
 - PROBLEMS
 - >> The IA **DID NOT** have a SL part of the application
 - Therefore, the 371 DOES NOT have a SL part of the application
 - Transfer requests are effective ONLY for transfer of the compliant CRF NOT the SL part of the application
 - » NO compliant CRF on file in the Office
 - » Request will not be granted
- Best resolution
 - Submit the SL text file as an amendment to the 371 (see slide 28)
 - » Can be obtained from applicant records, public PAIR, or PATENTSCOPE

April 2015



Example 2 of an IMPROPER Transfer Request

- An IA was filed with the RO/US via EFS-Web and includes
 - A compliant SL text file, which serves as part of the IA and as the CRF
- A new Con, CIP, or Div of the IA is filed with NO SL
 - Together with a request to transfer the compliant CRF from the IA
 - PROBLEMS
 - » The **new** application has **NO** SL part of the application
 - Transfer requests are effective ONLY for transfer of the compliant CRF NOT the SL part of the application
 - Request will not be granted
- Best resolution
 - Submit the SL text file as an amendment to the 371 (see slide 28)
 - » Can be obtained from applicant records, public PAIR, or PATENTSCOPE



Sequence Systems Service Center (\$3C) Help Desk

- For questions regarding
 - Sequence compliance
 - Request for Transfer of a CRF
- · (571) 272-2510
- STIC-SSSCHelpdesk@uspto.gov



Revision of WIPO ST.25 Standard for the Presentation of Nucleotide and Amino Acids Sequence Listings in Patent Applications

- ST.25 became effective in 1998, has not been revised since
- Committee on WIPO Standards (CWS) established a Task Force in October 2010 to revise ST.25
 - European Patent Office (EPO) designated as Task Force Leader
 - Work of the Task Force accomplished via a Wiki on the WIPO Web site
 Access restricted to Task Force members only
 - USPTO has 2 people on the Task Force and a team of people working on the standard
- Proposed revision is both technical and substantive
 - New standard will be based on XML
 - Substantive changes under discussion
- Adoption of the new standard at CWS has been delayed

- Effective date and transition provisions not yet determined



Thank You!

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