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Meeting of International Authorities Under the Patent Cooperation Treaty (PCT)

Twenty-Fourth Session Reykjavík, February 8 to 10, 2017

TRANSITION FROM WIPO STANDARD ST.25 TO WIPO STANDARD ST.26 FOR THE PRESENTATION OF NUCLEOTIDE AND AMINO ACID SEQUENCE LISTINGS

Document prepared by the International Bureau

BACKGROUND

1. At its reconvened fourth session, held in Geneva from March 21 to 24, 2016, the Committee on WIPO Standards (CWS) adopted WIPO Standard ST.26 "Recommended standard for the presentation of nucleotide and amino acid sequence listings using XML (eXtensible Markup Language)", as reproduced in Annex II to document CWS/4/7 and further amended as set out in the Annex to document CWS/4/7 Add.

2. The CWS also approved the following Editorial Note to be included in WIPO Standard ST.26 (see paragraphs 52 and 53 of the report of the session, document CWS/4BIS/16):

"The Committee on WIPO Standards (CWS) agreed to ask industrial property offices to postpone the preparations for implementation of this new WIPO Standard ST.26 until the recommendations for the transition from WIPO Standard ST.25 to the new Standard ST.26 is agreed on by the CWS at its next session to be held in 2017. Meanwhile, Standard ST.25 should continue to be used."

3. The CWS, at its reconvened fourth session, further noted a progress report on the work of the Sequence Listing (SEQL) Task Force established to handle Task No. 44 for the preparation of recommendations on the presentation of nucleotide and amino acid sequence listings based on XML (document CWS/4BIS/8). The CWS agreed to modify Task No. 44 and the work of the SEQL Task Force as follows (see paragraphs 83 and 84 of the Report of the session, document CWS/4BIS/16):

"83. As the new WIPO Standard ST.26 was adopted at this session, the CWS agreed to modify Task No. 44 as follows:

"Task No. 44: Prepare recommendations for the transition provisions from WIPO Standard ST.25 to ST.26; and a proposal for the revision of WIPO Standard ST.26, if needed".

"84. The CWS requested the SEQL Task Force to present a proposal for transition provisions from WIPO Standard ST.25 to ST.26 for consideration and approval at its next session."

4. The European Patent Office, as SEQL Task Force leader, has submitted a progress report and roadmap of the work of the Task Force for this meeting (document PCT/MIA/24/6).

5. In view of the relevance to the PCT of the transition from WIPO Standard ST.25 to ST.26, the SEQL Task Force invited the International Bureau to consult the PCT membership to provide input into its work to prepare a proposal for the transition between the two Standards, to be presented to the CWS at its next session to take place in 2017.

6. To follow up the above invitation from the Task Force, the International Bureau issued Circular C. PCT 1485/C. CWS 75, dated November 18, 2016, to Offices in their capacities as a receiving Office, International Searching and Preliminary Examining Authority and/or designated or elected Office under the PCT and/or in their capacity as a member of the CWS, and to certain non-governmental and organizations representing users of the PCT System. This Circular is reproduced in the Annex to this document

DISCUSSION OF RESPONSES TO CIRCULAR C. PCT 1485/C. CWS 75

7. Up to now, 29 IP Offices and two user groups have responded to the Circular. These responses are summarized in the following paragraphs.

Processing of Nucleotide and Amino Acid Sequences in International Applications after the Transition to WIPO Standard ST.26

8. Almost all responses supported the third possible option where international applications filed on paper containing nucleotide and amino acid sequences continued to be accepted, but with clear instructions for the receiving Office not to check the sequences for compliance with any PCT formality requirements under PCT Rule 26, beyond the requirements necessary for the purposes of uniform international publication, as proposed in paragraphs 21 to 24 of the Circular. These responses also supported the approach for handing sequence listings filed in an electronic format other than XML and therefore not in compliance with ST.26, as proposed in paragraph 26 of the Circular.

9. One response from an International Authority did not agree that the third option as described in paragraphs 21 to 24 of the Circular was the most appropriate one. This Authority wished to have a possibility for the applicant to provide an ST.26-compliant sequence listing on a physical medium to the receiving Office under Rule 13ter together with a paper international application. The sequence listing on the physical medium would be forwarded to the International Searching Authority and would not form part of the international application. This Authority also stated that it would be desirable to allow an ST.26 XML file on a physical medium to form part of a paper international application in certain situations. This possibility would avoid applicants incurring significant page fees or receiving Offices being required to handle lengthy paper sequence listings in cases where there was a power outage affecting electronic filing systems at an Office, or where an applicant had no internet connectivity. This Authority also did not agree with the approach for handling sequence listings filed in an electronic format other than XML, as proposed in paragraph 26 of the Circular, stating that this approach could result in the applicant filing a sequence listing as part of the international application in a format not accepted by the receiving Office, such as in ST.25 format after the transition to ST.26.

Transition Scenarios

10. All Offices that expressed a view on the transition scenario stated that they could accept the "big bang" scenario. This scenario was also the preferred scenario of practically all Offices. However, a few Offices voiced concern that smaller Offices would need to have the resources to handle files in XML after the transition. One Office stated that the "big bang" scenario should have a transitional period where filing of sequence listings would be possible in either ST.25 or ST.26 to enable users to adapt to the new standard.

International Applications filed after the Transition Date claiming Priority from an Application with <u>a Sequence Listing Filed in ST.25</u>

11. Responses expressed differing views on whether the translation date should be determined with reference to the international filing date of international applications, the priority date or whether the applicant should be given the choice.

12. Offices that preferred the priority date of the application to be reference for the transition date stated that, by using the international filing date, applicants could face problems with a sequence listing in the international application in ST.26 being supported by the priority document. These Offices emphasized that this problem should be avoided, even if the overlap period of Offices using both standards would be longer.

13. Offices that preferred the international filing date of the application indicated that this would shorten the overlap period where ST.25 and ST.26 would co-exist. These Offices also highlighted issues such as multiple priority dates, correction or addition of a priority claim and/or restoration of the right of priority, which would need to be taken into account if the priority date were used.

14. Some Offices believed that applicants, after the transition date, should have the flexibility to choose to continue filing a sequence listing in ST.25 if the application contained a sequence listing in compliance with this standard if they had concerns about the priority claim in the international application not being supported, or to choose to file in the new Standard. An Office opposed to this idea stated that this would require a check by formalities officers, preventing automated verification of sequence listings.

15. The user groups indicated that the transition date should either be determined with reference to the priority date of the application, or the applicant should be given the discretion to file a sequence listing in ST.25 or ST.26 when the application relied up a sequence listing filed in ST.25 from an earlier application as the basis for claiming priority.

Transition Date

16. Responses were divided between the three dates proposed in the Circular. One International Authority did, however, cite technical issues with implementing ST.26 by the latest of the three dates proposed, and indicated that the earliest date could be January 2022 or even as late as January 2024.

17. The Meeting is invited:

(i) to note the contents of the present document; and

(ii) to comment on any further issues which should be taken into account or investigated to ensure that International Authorities can receive and process sequence listings in ST.26 format reliably. [Annex follows]

TRANSITION FROM WIPO STANDARD ST.25 TO WIPO STANDARD ST.26 FOR THE PRESENTATION OF NUCLEOTIDE AND AMINO ACID SEQUENCE LISTINGS (reproduced from Circular C. PCT 1485/C. CWS 75)

C. PCT 1485/C. CWS 75

November 18, 2016

Madam, Sir,

Transition from WIPO Standard ST.25 to WIPO Standard ST.26 for the presentation of Nucleotide and Amino Acid Sequence Listings

1. This Circular is addressed to your Office in its capacity:

(a) as a receiving Office (RO), an International Searching Authority (ISA) and International Preliminary Examining Authority (IPEA) and/or a designated/elected Office (DO/EO) under the Patent Cooperation Treaty (PCT); and/or

(b) as a member of the Committee on WIPO Standards (CWS).

2. This Circular is also being sent to certain interested intergovernmental organizations and non-governmental organizations that are invited to attend the sessions of the PCT Working Group or of the CWS.

3. The purpose of this Circular is to consult on the transition between WIPO Standard ST.25 and ST.26, following the adoption by the CWS of WIPO Standard ST.26 "Recommended standard for the presentation of nucleotide and amino acid sequence listings using XML (eXtensible Markup Language)". In particular, in view of the relevance to the PCT of this transition, its purpose is to seek the input from PCT stakeholders, as requested by the CWS Sequence Listing Task Force. This input will then be taken into account by the Task Force, which intends to prepare a proposal for the transition between the two Standards for consideration by the CWS at its next session in 2017.

4. A draft of the present Circular has been discussed by the CWS Sequence Listing Task Force at a meeting of the Task Force held in Geneva on September 9, 2016, and was also made available for comments through the Task Force electronic forum. The present Circular takes into account comments and suggestions from the Task Force. In particular, the recommendation as to the most appropriate transition scenario, set out in paragraphs 29 and 30, below, and Annex II to the present Circular, was fully supported by the Task Force.

BACKGROUND

ADOPTION OF WIPO STANDARD ST.26

5. At its reconvened fourth session, held in Geneva from March 21 to 24, 2016, the CWS adopted WIPO Standard ST.26 "Recommended standard for the presentation of nucleotide and amino acid sequence listings using XML (eXtensible Markup Language)", as reproduced

in Annex II to document CWS/4/7 and further amended as set out in the Annex to document CWS/4/7 Add.¹

6. The CWS also approved the following Editorial Note to be included in WIPO Standard ST.26 (see paragraphs 52 and 53 of the report of the session, document CWS/4BIS/16):

"The Committee on WIPO Standards (CWS) agreed to ask industrial property offices to postpone the preparations for implementation of this new WIPO Standard ST.26 until the recommendations for the transition from WIPO Standard ST.25 to the new Standard ST.26 is agreed on by the CWS at its next session to be held in 2017. Meanwhile, Standard ST.25 should continue to be used."

7. The CWS, at its reconvened fourth session, further noted a progress report on the work of the Sequence Listing (SEQL) Task Force established to handle Task No. 44 for the preparation of recommendations on the presentation of nucleotide and amino acid sequence listings based on XML (document CWS/4BIS/8). The CWS agreed to modify Task No. 44 and the work of the SEQL Task Force as follows (see paragraphs 83 and 84 of the Report of the session, document CWS/4BIS/16):

"83. As the new WIPO Standard ST.26 was adopted at this session, the CWS agreed to modify Task No. 44 as follows:

"Task No. 44: Prepare recommendations for the transition provisions from WIPO Standard ST.25 to ST.26; and a proposal for the revision of WIPO Standard ST.26, if needed".

"84. The CWS requested the SEQL Task Force to present a proposal for transition provisions from WIPO Standard ST.25 to ST.26 for consideration and approval at its next session."

8. In view of the relevance to the PCT of the transition from WIPO Standard ST.25 to ST.26 (see below), the SEQL Task Force has invited the International Bureau to consult the PCT membership to provide input into its work to prepare a proposal for the transition between the two Standards, to be presented to the CWS at its next session to take place in 2017.

RELATIONSHIP BETWEEN THE PCT SEQUENCE LISTING STANDARD, WIPO STANDARD ST.25 AND WIPO STANDARD ST.26

9. WIPO Standard ST.25 consists of a single paragraph, recommending that Offices apply the PCT Sequence Listing Standard (as set out in Annex C to the PCT Administrative Instructions) *mutatis mutandis* to all patent applications other than PCT international applications, with the proviso that certain provisions which are specific to the PCT procedures and requirements may not be applicable to patent applications other than PCT international applications.

10. Thus, at present, all of the substantive provisions making up the international sequence listing standard are contained in Annex C to the Administrative Instructions under the PCT rather than, as one would perhaps expect, in WIPO Standard ST.25. Looking back, one of the main reasons for this somewhat unusual relationship between the two Standards (with the WIPO Standard referring to the PCT Standard, rather than the other way around) appears to be that Member States, at the time of the establishment of the first common sequence listing standard back in 1997/1998, found it preferable "to get things off the ground" within the framework of the PCT. The applicability of the PCT Standard was then broadened to applications filed outside of the PCT by simply referring to the PCT Standard in WIPO Standard ST.25.

¹ See WIPO's website at: http://www.wipo.int/meetings/en/details.jsp?meeting_id=39402

11. As a consequence, the PCT Sequence Listing Standard set out in Annex C of the PCT Administrative Instructions (and thus WIPO Standard ST.25) contains not only details of the presentation of sequence listings but also processing arrangements which are specific to the PCT System only. For example, Annex C contains details on the presentation of sequence listings not forming part of the international application as filed but submitted for the purposes of international search or international preliminary examination only. Moreover, the PCT Sequence Listing Standard (and thus WIPO Standard ST.25) contains details with regard to the presentation of sequence listings contained in both international applications filed on paper and in electronic form.

12. By contrast, WIPO Standard ST.26 is "filing-route neutral", that is, it does not contain any processing arrangements specific to national, regional or international applications but, in its entirety, is applicable to all patent applications, be they national, regional or international. In addition, ST.26 sets out the requirements for the presentation of sequence listings in XML format only; it does not cover the presentation of sequences contained in applications filed on paper or of sequences presented in electronic formats other than XML, such as PDF. Further details on the main differences between WIPO Standards ST.25 and ST.26 are summarized in Annex I to the present Circular.

MODIFICATION OF THE PCT STANDARD FOR THE PRESENTATION OF NUCLEOTIDE AND AMINO ACID SEQUENCE LISTINGS

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13. Consequential on the establishment of new WIPO Standard ST.26—filing route neutral but limited in scope to the presentation, contents and structure of sequence listings in XML— it is necessary to modify the PCT Administrative Instructions relating to the presentation of sequence listings, along the lines of what had been initially discussed and generally supported by the PCT Working Group at its fourth session in June 2011 (see document PCT/WG/4/9 and paragraphs 180 to 188 of the report of the session, document PCT/WG/4/17).

14. The aim of such modification of the PCT Administrative Instructions would be to achieve two things: first, to provide that, in order to be in compliance with the newly applicable PCT Standard, sequence listings contained in international applications will have to be presented in XML format, as required under WIPO Standard ST.26. And second, the PCT Administrative Instructions should only deal with processing arrangements which are specific to the PCT and not therefore covered by WIPO Standard ST.26.

15. Specific proposals of necessary modifications to the PCT Administrative Instructions will be the subject of one or more further PCT Circulars at a later date. At this stage, the present Circular only invites comments on the broad approach to be taken with regard to two issues:

(i) the PCT specific processing arrangements, to be set out in modified PCT Administrative Instructions, relating to international applications filed on paper containing disclosures of nucleotide and amino acid sequences and international applications filed in electronic form containing such disclosures in an electronic document format other than ST.26 compliant XML (such as PDF), as set out in paragraphs 16 to 26, below; and

(ii) the transition from WIPO Standard ST.25 to WIPO Standard ST.26, as set out in paragraphs 27 to 30, below, and Annex II to the present Circular.

NUCLEOTIDE AND AMINO ACID SEQUENCES DISCLOSED IN INTERNATIONAL APPLICATIONS FILED ON PAPER

16. In general, it is to be noted that the PCT Regulations assume that the applicant may always file an international application on paper, including one which discloses nucleotide and amino acid sequences.

17. At present, a small but significant proportion of international applications containing nucleotide and amino acid sequences are filed on paper (approximately 4 per cent in 2015). WIPO Standard ST.25 "caters" for such international applications filed on paper by defining the requirements relating to the presentation of sequence listings in terms of layout ("nucleotide sequences or amino acid sequences are set out as groups of characters representing up to 60 bases or 16 amino acids per line"). While the preferred arrangement is that the sequence listing is provided in electronic form as an ST.25-compliant text file, the requirements can equally be met by submitting a paper print-out or image-based PDF view of the sequence listing (prepared using the PatentIn software), although an International Authority may later invite the applicant under Rule 13 ter to file a sequence listing in an ST.25-compliant electronic form for international search and/or international preliminary examination. In the case of short sequence listings, the sequence listing could even be provided by typing the characters onto a piece of paper. ST.25 also sets out specific provisions concerning page layout and numbering of pages for any sequence listing contained in an international application filed on paper.

18. WIPO Standard ST.26, on the other hand, is specifically an XML standard, designed to facilitate the computerized searching of sequence listing data and to allow the data to be exchanged in electronic form and introduced into computerized databases. It does not cover any details with regard to the presentation of sequences contained in applications filed on paper. As a consequence, as far as the PCT is concerned, it is necessary to consider how international applications filed on paper containing disclosures of sequences should be processed after the transition to ST.26.

19. A first possible option would be to continue to apply WIPO Standard ST.25 as the applicable standard for the presentation of a sequence listing in an international application filed on paper, to be followed up by the furnishing, under Rule 13*ter*, of a sequence listing in compliance with WIPO Standard ST.26 for the purposes of international search only. However, since the substantive contents of Standards ST.25 and ST.26 differ, any sequence listing prepared in compliance with ST.25 would, by definition, differ in content from any sequence listing prepared in compliance with ST.26 compliant sequence, any attempted "transformation" by the applicant of an ST.25 compliant sequence listing filed on paper to an ST.26 compliant sequence listing in XML to be furnished for the purposes of international search would not create an identical sequence listing. Rather, it would require the applicant to change the formatting and, in most if not all cases, to manually add further information, thus potentially raising "added matter" issues.

To avoid any such "added matter" issues, a second possible option would be to again 20. allow so-called "mixed mode" applications, that is, to allow an applicant to file an international application on paper together with a sequence listing in an ST.26 compliant XML file. Such a possibility to file international applications on paper together with the sequence listings in electronic form was possible between 2001 and 2009. At the time of its introduction in 2001, it had been intended as temporary solution, pending the wide availability of fully electronic systems, aimed at addressing the problem of very large sequence listings being filed on paper, which were both difficult to process and, from the applicant's perspective, extremely expensive, due to the number of page fees payable. The option of mixed mode sequence listing applications was abolished with effect from July 1, 2009, once fully electronic filing systems became available to applicants, whether through a national receiving Office or the receiving Office of the International Bureau, which could handle extremely large sequence listings provided that they were uploaded in text format. Reverting to mixed-mode applications to cater for the filing of international applications on paper which contain disclosure of sequences would be one possible option; however, given the universal availability of electronic filing systems and the previously experienced complexity of "mixed mode" filings, this would—in the view of the International Bureau—not appear to be the preferred option.

21. A third possible option which would also avoid "added matter" issues would be to continue to accept international applications filed on paper containing nucleotide and amino acid sequences, but with clear instructions for the receiving Office to not check the sequences for compliance with any PCT formality requirements under PCT Rule 26, beyond the requirements necessary for the purposes of uniform international publication. In essence, any sequences presented on paper, even if presented in the form of a print-out of a ST.26 compliant sequence listing, would not be considered as a sequence listing in compliance with the PCT Standard, but would instead be considered as a disclosure of sequences. The receiving Office would merely check the sheets containing the disclosed sequences for compliance with the requirements necessary for the purposes of reasonably uniform international publication.

22. It would then be left to the International Searching Authority to invite the applicant under Rule 13*ter* to furnish a sequence listing in compliance with ST.26 for the purposes of the international search, accompanied by a statement by the applicant that the sequence listing does not go beyond the disclosure of the international application as filed. Any such sequence listing ST.26 compliant sequence listing, if submitted by the applicant, would then be used for the purposes of international search only and would not form part of the international application.

23. Similarly, an International Preliminary Examining Authority would invite the applicant, under Rule 13*ter*, to furnish an ST.26 compliant sequence listing for the purposes of international preliminary examination, accompanied by a statement by the applicant that the sequence listing does not go beyond the disclosure of the international application as filed. Any such sequence listing would not form part of the international application, unless the applicant incorporated it into the description by amendment under Article 34.

24. This alternative approach would be very similar to the way in which many receiving Offices today, in practice, handle sequence listings contained in international applications filed on paper, recognizing that it is practically impossible for a formalities examiner, except for very short sequence listings with only a few lines of characters, to perform a meaningful "formality check" on a sequence listing for compliance with ST.25. Thus, the approach taken by most receiving Offices today is not to check for compliance of a sequence listing with WIPO Standard ST.25 but to leave it to the International Searching Authority or the International Preliminary Examining Authority to invite the applicant, if necessary, to furnish an ST.25 compliant sequence listing under Rule 13*ter*.

25. In the view of the International Bureau, the third option discussed in paragraphs 21 to 24, above, would appear most appropriate.

NUCLEOTIDE AND AMINO ACID SEQUENCES FILED IN A NON-COMPLIANT ELECTRONIC FORMAT

The same approach as discussed in paragraphs 21 to 24, above, could be taken with 26. regard to international applications filed in electronic form containing disclosure of sequences in electronic form but in an electronic document format other than XML and therefore not in compliance with WIPO Standard ST.26. In this situation, while the receiving Office would be able to identify non-compliance on import of the purported sequence listing due to the electronic document format of the file, the formalities examiner at the receiving Office would not comment on the form of presentation. Instead, the receiving Office would leave it to the International Searching Authority to invite the applicant, under Rule 13ter, to furnish an ST.26 compliant sequence listing, accompanied by a statement by the applicant that the sequence listing does not go beyond the disclosure of the international application as filed. Such sequence listing, if submitted by the applicant, would be used for the purposes of international search only and would not form part of the international application. This approach would therefore be similar to the current handling of international applications with a sequence listing submitted in an electronic form that is not compliant with ST.25, such as a PDF document containing a scanned image.

TRANSITION FROM WIPO STANDARD ST.25 TO WIPO STANDARD ST.26

AVAILABILITY OF SOFTWARE TOOL

27. A prerequisite for making the transition to ST.26 would appear to be the availability of a dedicated software tool to enable applicants to prepare sequence listings and verify that such sequence listings are in compliance with the new Standard ST.26 for Offices to process the application containing these sequence listings, and for viewing of these sequence listings in a human readable form. The International Bureau will develop such an authoring and validation tool and will make it available at the time of switching to ST.26.

While, ideally, it would further appear desirable for such a tool to have a data 28. transformation function which would enable sequence listings prepared in an ST.25 compliant format to be transformed into an ST.26 compliant format (of particular importance in the context of the question whether to provide for a special transitional arrangement allowing international applications claiming priority from earlier applications containing ST.25 sequence listings to be filed using ST.25 after the general commencement date: see paragraphs 21 to 23 in Annex II to the present Circular), unfortunately, it would not appear to be possible to provide this as a fully automated function. As indicated in paragraph 19, above, since the substantive contents of both Standards differs, any sequence listing prepared in compliance with ST.25 would differ in contents from any sequence listing prepared in compliance with ST.26; thus, any transformation from ST.25 to ST.26 would typically require further information to be added manually by the applicant to the transformed sequence listing and might involve some substantive data being lost. As a result, in the context of the question of providing corrections to address defects in an international application where originally filed sequences were not in the form of a sequence listing in compliance with ST.26, such transformations would potentially result in a sequence listing which was not substantially identical to what had been originally filed, potentially raising "added matter" issues. However, the International Bureau will study the possibility to include. in the tool referred to in paragraph 27, above, a function for an "assisted transformation" which would allow an applicant to import a sequence listing prepared in an ST.25 compliant format and to further fill-in manually any missing ST.26 compliant information.

IMPLEMENTATION OF WIPO STANDARD ST.26 IN THE PCT

29. On the assumption that a dedicated software tool is made available for authoring and verifying sequence listings in compliance with ST.26, Annex II to the present Circular discusses possible scenarios for making the transition from ST.25 to ST.26 at receiving Offices, International Searching and Preliminary Examining Authorities and designated/elected Offices under the PCT.

30. As further explained in Annex II, in the view of the International Bureau, and fully supported by the CWS Sequence Listing Task Force (see paragraph 4, above), the most workable transition would be for all Offices to agree on a "big bang" scenario, that is, to agree on a transition date as of which all Offices in their various PCT capacities would move from ST.25 to ST.26 as the only valid format for the filing of sequence listings under the PCT (with possible special arrangements for applications claiming priority from earlier applications using ST.25). Sequence listings contained in an international application with an international filing date earlier than the transition date, and sequence listings submitted on or after the transition date but in relation to an international application with an international filing date earlier than the transition date in an international application with an international filing date earlier than the transition date, would need to be submitted and processed in compliance with ST.25. Sequence listings contained in an international application with an international filing date on or after the transition date or submitted in relation to such an application would need to submitted and processed in compliance with ST.26.

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RESPONSES TO THIS CIRCULAR

31. Your Office is invited to provide comments on the proposed approach concerning the processing of nucleotide and amino acid sequences in international applications after the transition to WIPO Standard ST.26, as discussed in paragraphs 13 to 26, above, as well as the issues explored in Annex II to the present Circular relating to the question as to how to best transition from WIPO Standard ST.25 to WIPO Standard ST.26. A Questionnaire in Annex III to the present Circular has been provided for your Office to submit comments. In particular, Offices are invited to indicate a preferred transition date for the move from WIPO Standard ST.25 to ST.26 from among the dates proposed in Question V of the Questionnaire.

32. Any comments received by the date indicated below will be taken into account in the feedback to be provided to the SEQL Task Force as input into its work to prepare a proposal for the transition between the two Standards, to be presented to the CWS at its next session to take place in 2017.

33. Responses should be sent, preferably by e-mail, to Mr. Claus Matthes, Senior Director, PCT Legal and International Affairs Department (e-mail: <u>claus.matthes@wipo.int;</u> fax: (+41-22) 338 7150; tel: (+41-22) 338 9809) by December 20, 2016. Responses to this Questionnaire may be submitted in any of the six official languages of the United Nations (Arabic, Chinese, English, French, Russian and Spanish).

Yours sincerely,

Francis Gurry Director General

Enclosures: Annex I – Main Differences between WIPO Standards ST.25 and ST.26 Annex II - Implementation of WIPO Standard ST.26 in the PCT Annex III - Questionnaire

Annex I to Circular C. PCT 1485/C. CWS. 75

MAIN DIFFERENCES BETWEEN WIPO STANDARDS ST.25 AND ST.26

	ST.25	ST.26
Format	Text	XML
Standalone document	No Refers to the text of PCT AI Annex C	Yes
PCT Procedural Requirements	Yes	No
Sequences with <10 specific nucleotides <4 specific amino acids	Not prohibited	Prohibited
Sequences with D amino acids	Not required	Required
Branched sequences	Not required	Required – linear regions
Thymidine and uracil	"t" is thymidine and "u" is uracil	"t" is both thymidine in DNA and uracil in RNA
Annotations	Feature keys only	Enhanced Feature keys Qualifiers
Annotation of variant sequences	Not standardized	Standardized
Location descriptors	Not standardized	Standardized
Free text field	Max – 260 characters (4 lines of 65 characters/line)	Max – 1,000 characters
Bibliographic references	Provided for	Not provided for

[Annex II (of Circular C. PCT 1485/C.CWS 75 follows]

Annex II to Circular C. PCT 1485/C. CWS. 75

IMPLEMENTATION OF WIPO STANDARD ST.26 IN THE PCT

TRANSITION SCENARIOS

1. In terms of the transition between ST.25 to ST.26 at any given Office, the following three scenarios have been proposed in the SEQL Task Force, as illustrated in Figure 1, below.

"Big Bang" – all Offices, in their capacity as receiving Offices, (a) International Authorities and designated and elected Offices, would agree on a date for the transition from ST.25 to ST.26 for the filing of sequence listings in new applications ("the transition date"). Sequence listings contained in an international application with an international filing date earlier than the transition date (or, alternatively, all international applications with a priority date earlier than the transition date, see paragraphs 21 to 23, below), and sequence listings submitted on or after the transition date but in relation to an international application with an international filing date earlier than the transition date, would need to be submitted and processed in compliance with ST.25. Sequence listings contained in an international application with an international filing date on or after the transition date, and sequence listings submitted on or after the transition date in relation to an international application with an international filing date on or after the transition date, would need to submitted and processed in compliance with ST.26.

(b) <u>"Some go ahead"</u> – A group of Offices, in their capacity as receiving Offices, including the International Bureau in its capacity as a receiving Office, would agree on a transition date and, as of that date, accept sequence listings for new international applications with an international filing date on or after this date only in ST.26. Other receiving Offices would continue to require sequence listings in ST.25 and make the transition to ST.26 at a later date, at their choice, until eventually all Offices will have moved to ST.26. This scenario would require that all International Authorities and all designated and elected Offices would, as of the transition date, accept sequence listings in both ST.25 and ST.26 formats until the very last receiving Office had moved to accept sequence listings in ST.26 only.

(c) <u>"Each at its own pace"</u> – receiving Offices would independently make the transition from ST.25 to ST.26 until all Offices only accepted ST.26 sequence listings for new applications. As under the "Some go ahead" scenario, this scenario would also require that all International Authorities and all designated and elected Offices would, as of the transition date, accept sequence listings in both ST.25 and ST.26 formats until the very last receiving Office had moved to accept sequence listings in ST.26 only.

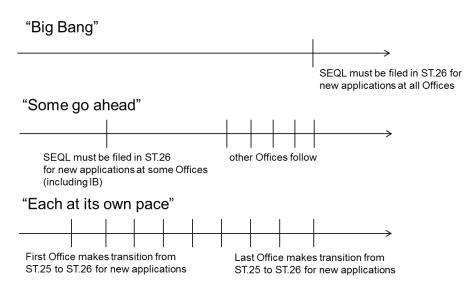


Figure 1: Proposed Transition Scenarios

<u>Big Bang</u>

2. Under the "big bang" scenario, sequence listings related to new international applications with an international filing date on or after the transition date (or, alternatively, all international applications with a priority date earlier than the transition date, see paragraphs 21 to 23, below) would be required to be in compliance with ST.26. As of the transition date, the receiving Office, the International Searching Authority, the International Preliminary Examination Authority and the designated/elected Offices would need to be able to process any sequence listing contained in these applications.

3. As of the transition date, the receiving Office would need to be able:

(a) in respect of all international applications with an international filing date on or after the transition date, to receive sequence listings in ST.26 and forward them to the International Bureau and International Searching Authority;

(b) in respect of all international applications with an international filing date earlier than the transition date, to continue to receive sequence listings in ST.25 and forward them (for example, sequence listings not forming part of the application) to the International Bureau and International Searching Authority.

4. As of the transition date, the International Searching Authority would need to be able:

(a) in respect of all international applications with an international filing date on or after the transition date, to receive and process sequence listings in ST.26; the International Searching Authority could perform an "informal" transformation of a sequence listing from ST.26 to ST.25, or *vice versa*, for its own benefit to perform the search, if it so wished (noting that this would frequently either require manual completion or else lack some information which could not be transformed automatically); however, the applicant could not be asked to furnish a sequence listing for the purposes of international search in any different format (such as ST.25) if the sequence listing contained in the international application with an international filing date on or after the transition date had been presented in compliance with ST.26. A similar case would apply for the purposes of supplementary international search and international preliminary examination.

(b) in respect of all international applications with an international filing date earlier than the transition date, to continue to receive and process sequence listings in ST.25 (for example, sequence listings not forming part of the application).

5. As of the transition date, designated and elected Offices would need to be able:

(a) in respect of all international applications entering the national phase with an international filing date on or after the transition date, to receive and process sequence listings complying with ST.26; while national phase entry would normally occur at least 18 months after the international filing date, given the 30 month time limit from the priority date stipulated in PCT Articles 23 and 39, an applicant may make an express request for early national phase entry at any time after the filing of an international application; therefore, any designated or elected Office would have to be equipped to accept sequence listings in international applications in compliance with ST.26 from the transition date onwards;

(b) in respect of all international applications with an international filing date earlier than the transition date, to continue to receive and process sequence listings in ST.25.

6. Even under the "big bang" scenario, there will be a considerable overlap period where Offices will be required to receive, process and publish sequence listings in both ST.25 and ST.26. This overlap period cannot be shorter than 30 months at any Office, and would be significantly longer in respect of Offices which have set a later deadline for national phase entry or carry out substantive examination during the national phase, during which the applicant may be required (for example, in case of the need to file a divisional application) to re-furnish a sequence listing.

7. Consideration will thus have to be given to the question as to whether current Annex C of the PCT Administrative Instructions should be maintained, at least for a transitional period, to remain applicable in respect of international applications containing sequence listings with an international filing date before new WIPO Standard ST.26 becomes mandatory, in addition to a new Annex to the Administrative Instructions (which could be called Annex C-*bis*), applicable in respect of international applications filed on or after the transition date.

Some go ahead

8. Under the "some go ahead" scenario, a group of receiving Offices, including the International Bureau in its capacity as a receiving Office, would agree on a transition date for switching from ST.25 to ST.26 for the filing of sequence listings in international applications filed on or after the transition date. Other Offices not belonging to this group would make the transition at a later date of their own choice until the very last Office will have accepted filings in ST.26 only.

9. As of the transition date, some receiving Offices, including the International Bureau, would require sequence listings in international applications with an international filing date on or after the transition date to comply with ST.26, while some other receiving Offices would still require sequence listings to comply with ST.25. The relevant standard for a sequence listing specified in PCT Rule 5.2 (and

further detailed in the Administrative Instructions in present Annex C (ST.25) and "Annex C-*bis*" (ST.26) would therefore depend on the receiving Office; the International Bureau would publish which standard each receiving Office applied in the PCT Applicant's Guide. A receiving Office not belonging to the initial group accepting sequence listings in ST.26 would inform the International Bureau of the date as of which it was ready to make the transition from ST.25 to ST.26 for updating the PCT Applicant's Guide.

10. As the International Bureau is a competent receiving Office for all PCT Contracting States, after the transition date under the "some go ahead" scenario, all applicants would have the possibility to file a sequence listing in compliance with ST.26. For international applications from applicants from Contracting States in respect of which the International Bureau is the only competent receiving Office and those from applicants from Contracting States in respect of which all other competent receiving Offices had made the transition from ST.25 to ST.26, applicants would only be able to file sequence listings in ST.26. The option to file sequence listings in ST.25 would remain for applicants from a Contracting State having at least one competent receiving Office still using ST.25 until all competent receiving Offices for that State had made the transition to ST.26.

As indicated above, the applicable standard under PCT Rule 5.2 for sequence 11. listings would, in general, depend on the receiving Office. However, since the International Bureau as receiving Office would, after the transition date, belong to the group of Offices which will have gone ahead and only accept ST.26 sequence listings in respect of international applications with an international filing date on or after the transition date, after the transition date, all International Searching Authorities would be required to search international applications with an international filing date on or after the transition date containing sequence listings in ST.26. An International Searching Authority would also have to search international applications containing sequence listings in ST.25 if an Authority was competent for a receiving Office yet to make the transition to ST.26 (in addition to being required to process sequence listings related to international applications with an international filing date prior to the transition date). Most International Searching Authorities could therefore experience a prolonged period where parallel processing of sequence listings in ST.25 and ST.26 would be required.

12. A similar prolonged period of parallel processing of sequence listings in ST.25 and ST.26 could be expected at some International Preliminary Examining Authorities, noting that many Authorities are competent for applications in respect of which they have performed the international search.

13. Furthermore, an International Searching Authority offering supplementary international searches may not be able to complete a full transition to ST.26 even if the last receiving Office for which it was competent to act as the "main" International Searching Authority no longer accepted sequence listings filed in compliance with ST.25. An International Searching Authority that offers supplementary international search is competent to carry out supplementary international search for all international applications except those where the Authority itself performed the "main" international search. Thus, an applicant could file at a receiving Office still accepting sequence listings in ST.25 and request supplementary international search at any Authority offering the service (unless the Authority had performed the "main" international search). Thus, under the "some go ahead" scenario, International Authorities offering supplementary international search would effectively be required to accept applications filed with sequence listings in ST.25 until it was no longer accepted by any receiving Office.

14. In view of PCT Article 27(1) and the possibility for an applicant to request early national phase entry at any time after the filing of the international application, under the "some go ahead" scenario, a designated or elected Office would have to be equipped to accept sequence listings in compliance with ST.26 from the transition date onwards, and would also be required to continue to accept sequence listings filed in compliance with ST.25 if this was the standard required by the receiving Office where the international application was filed. The designated or elected Office would therefore need to be able to work with both standards from the transition date until the very last receiving Office had made the transition to ST.26.

15. In summary, while the "some go ahead" scenario would permit a group of receiving Offices to make the transition between ST.25 and ST.26 earlier than other receiving Offices, which could switch to the new standard at their own pace at a later date, all designated and elected Offices and most International Searching Authorities would be required to accept sequence listings in both ST.25 and ST.26 from the transition date of the first group of receiving Offices until all receiving Offices had moved to ST.26. An Office that had made the transition to ST.26 in its capacity as a receiving Office would still be required to accept ST.25 in its capacity as a designated or elected Office, and an Office yet to make the transition to ST.26 in its capacity as a receiving Office would have to accept ST.26 in its capacity as a designated or elected Office.

Each at its own pace

16. Under the "each at its own pace" scenario, each receiving Office would set its own date for making the transition from ST.25 to ST.26. The relevant standard for a sequence listing specified in PCT Rule 5.2 would depend on the receiving Office, and the International Bureau would publish the standard each receiving Office applied in the PCT Applicant's Guide. The applicant would thus only have the possibility to file a sequence listing in ST.26 if the applicant's "own" competent receiving Office or the International Bureau in its capacity as a receiving Office for applicants from all Contracting States had made the transition.

17. This scenario would have a similar effect to the "some go ahead" scenario at the International Searching Authority, International Preliminary Examining Authority and designated or elected Office by creating a prolonged period where parallel processing of ST.25 and ST.26 would be required. For designated and elected Offices, parallel processing would start as soon as the first receiving Office had made the transition to ST.26 and would not finish until after the very last receiving Office had ceased to accept sequence listings filed in ST.25. Furthermore, in a similar way to the "some go ahead" scenario, an Office that had made the transition to ST.26 in its capacity as a receiving Office, and an Office yet to make the transition to ST.26 in its capacity as a receiving Office would have to accept ST.26 in its capacity as a receiving Office.

Recommendation

18. As PCT Article 27(1) requires a designated or elected Office to accept a sequence listing filed in compliance with applicable PCT standard, <u>the "big bang"</u> <u>scenario</u>, that is, establishing a single transition date between ST.25 and ST.26 for new international applications with an international filing date on or after this transition date, would provide greater certainty for Offices in the national phase than allowing Offices, in their capacity as a receiving Office, to set their own transition date. Not only would designated/elected Offices be able to prepare for the transition

to ST.26 based on an agreed transition date, but the overlap period where sequence listings in both ST.25 and ST.26 would need to be processed would be kept to a minimum.

19. For International Authorities, an agreed transition date to ST.26 under the "big bang" scenario would allow Authorities to prepare for processing sequence listings in the new standard after this date. In addition, by requiring all receiving Offices to switch from ST.25 to ST.26 on the transition date, a protracted period of International Authorities using both standards is avoided, whose length would be determined by the very last receiving Offices transferring to ST.26.

20. Thus, in the view of the International Bureau, and fully supported by the CWS Sequence Listing Task Force (see paragraph 4 in the main body of the present Circular, the "big bang" scenario would clearly be the most workable transition for the PCT. By agreeing on common transition date, Offices in their various PCT capacities would be able to prepare for the transition to ST.26 without needing to be ready to accept the new standard due to another Office making an early transition, or being required to continue to accept applications in ST.25 due to another Office making a late transition.

Determination of the Transition Date to be based on the International Filing Date or on the Priority Date?

21. One important issue to be addressed is whether the transition date should be determined with reference to the international filing date of international applications (that is, whether ST.26 should be applied to all international applications with an international filing date on or after the transition date), or with reference to the claimed priority date of international applications (that is, whether ST.25 should continue to be applied to all international applications with an international filing date on all international applications with an international filing date on or after the transition date), or with reference to the claimed priority date of international applications (that is, whether ST.25 should continue to be applied to all international applications with an international filing date on or after the transition date but claiming priority from an earlier application filed before the transition date containing a sequence listing in ST.25 format). Table 1 considers the effect of these alternatives on the validity of the priority claim and on the overlap period during which an Office or Authority would be required to handle applications with sequence listings in both ST.25 and ST.26 formats:

Transition Date based on International Filing Date of International Application	Transition Date based on Priority Date of International Application
Uncertainty in respect of the validity of the priority claim if the sequence listing contained in the international application is submitted in ST.26 (since it may contain additional matter over a sequence listing of "the same" nucleotide or amino acid submitted in ST.25 as part of the earlier application)	Clear validity of priority claim (since ST.25 compliant sequence listing is contained in both the international application and the earlier application)
Short overlap period at receiving Office, limited to a few months (to handle corrections under Rule 26, incorporation by reference cases, etc. in respect of applications filed before transition date)	Long overlap period at receiving Office of at least 14 months (applicant has possibility to request restoration of right of priority under PCT Rule 26 <i>bis</i>)

Short overlap period at International Searching Authority of a few months (due to variation in transmission times from receiving Office, need to perform additional searches due to lack of unity of invention)	Long overlap period at International Searching Authority (the time limit under PCT Rule 42 for some international applications with sequence listings filed in ST.26 will precede the time limit of other international applications with sequence listings filed in ST.25; requests for rectifications of obvious mistakes)
Long overlap period at International	Long overlap period at International
Preliminary Examining Authority (for final	Preliminary Examining Authority (for final
cases filed in ST.25, time limit for making	cases filed in ST.25, time limit for making
a demand under Rule 54 <i>bis</i> is the later of	a demand under Rule 54 <i>bis</i> is the later of
22 months from priority date or 3 months	22 months from priority date or 3 months
from establishment of international	from establishment of international
search report; requests for rectifications	search report; requests for rectifications
of obvious mistakes).	of obvious mistakes).
Long overlap period at	Long overlap period at
designated/elected Office (national	designated/elected Office (national
phase entry time limit based on priority	phase entry time limit based on priority
date, but applicant may request early	date, but applicant may request early
entry)	entry)

Table 1:	Application	of Transition	Date in the	Big Bang	Scenario

22. Basing the transition date on the international filing date of the international application would provide a relatively short overlap period for receiving Offices and the International Searching Authority, but would create uncertainty for the applicant with regard to the validity of the priority claim, as the standard for sequence listings in the international application would differ from that used in an earlier application being used as the basis for claiming priority. On the other hand, basing the transition date on the priority date would lengthen the overlap period at receiving Office and the International Searching Authority, but provide greater certainty for applicants. However, it would likely also need an absolute cutoff date based on the international filing date (for example, 24 months after the transition date) to avoid a problem where a few national Offices were still accepting ST.25 compliant sequence listings and did not require a transition to ST.26 compliant listings for their national filings for an extended period following the transition date.

23. A third possibility could be for the applicant who had filed an international application with an international filing date on or after the transition date claiming priority from an earlier application filed before the transition date to be provided with a choice between filing any sequence listing in ST.25 or ST.26. This would allow applicants to use ST.26 as early as possible, but retain the possibility to file in ST.25 to address concerns such as additional matter, which might arise if the applicant would be required to transform a sequence listing from ST.25 to ST.26.

[Annex III (of Circular C. PCT 1485/C.CWS. 75) follows]

Annex II to Circular C. PCT 1485/C. CWS. 75

QUESTIONNAIRE

TRANSITION FROM WIPO STANDARD ST.25 TO ST.26

RESPONSE FROM:

Name of responsible official:

On behalf of [Office]:

I. INTRODUCTORY QUESTIONS

1. Please indicate the approximate number of international applications with sequence listings or sequence disclosures that your Office receives per year:

- (a) as a receiving Office:
- (b) as a designated/elected Office:
- (c) as an International Searching Authority:
- (d) as an International Preliminary Examining Authority:

2. Please indicate the approximate number of national or regional patent applications outside of the PCT that your Office receives per year:

II. PROCESSING OF NUCLEOTIDE AND AMINO ACID SEQUENCES IN INTERNATIONAL APPLICATIONS AFTER THE TRANSITION TO WIPO STANDARD ST.26

Please provide your comments on the proposed approach after the transition to WIPO Standard ST.26 with regard to disclosures of nucleotide and amino acid sequences in international applications filed on paper or submitted in an electronic document format other than XML, as set out in paragraphs 16 to 26 of the main body of the present Circular.

III. TRANSITION SCENARIOS

Please provide your comments on the transition scenarios discussed in Annex II of the present Circular.

In particular, please indicate whether you agree with the analysis in this Annex that the "big bang" scenario is the most workable solution in the PCT (that is, fixing a transition date for all Offices, whether acting in the capacity as a receiving Office, International Searching Authority, International Preliminary Examining Authority or designated/elected Office under the PCT, to switch to WIPO Standard ST.26 as the relevant standard for the filing of sequence listings in relation to international applications with an international filing date on or after the transition date)?

IV. POSSIBLE SPECIAL PROVISION FOR INTERNATIONAL APPLICATIONS CLAIMING PRIORITY FROM EARLIER APPLICATIONS CONTAINING SEQUENCE LISTINGS IN COMPLIANCE WITH ST.25

Please provide your comments on the analysis set out in paragraphs 21 to 23 of Annex II to the present Circular on whether the transition date should be determined with reference to the international filing date of international applications (that is, whether ST.26 should be applied to all international applications with an international filing date on or after the transition date), or with reference to the priority date of international applications (that is, whether ST.25 should continue to be applied to all international applications with an international applications with an international filing date on or after the transition date), or with reference to the priority date of international applications (that is, whether ST.25 should continue to be applied to all international applications with an international filing date on or after the transition date but claiming priority from an earlier application filed before the transition date).

In particular, please indicate any preference on whether the transition date and WIPO Standard to be used for the presentation of any sequence listings should be based on the international filing date of the international application, the priority date of the application, or whether the applicant should be given the choice of using the previous (ST.25) or new standard (ST.26) in such applications.

V. PROVISIONAL TRANSITION DATE

On the assumption that an authoring and verification tool is developed and deployed by the end of 2018, please indicate a preferred transition date to move from WIPO Standard ST.25 to ST.26.

1.	July 1, 2019	
2.	July 1, 2020	
3.	July 1, 2021	

4. Other (please indicate a preferred other transition date):

[End of Annex and of document]